

EXHIBIT 34

3 In re: Bair Hugger Forced Air
Warming Products Liability
4 Litigation

MDL No. 2666

19 Reported by:
20 SUSAN PERRY MILLER, RDR, CRR, CRC
21 JOB NO. 124787

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VIDEO TECHNICIAN: Robert Birdsall
--ooOo--

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Y. DAVID
(Tuesday, August 1, 2017, 9:16 a.m.)
THE VIDEOGRAPHER: Good morning.
This is the start of the Deposition of
Yadin David, Dr. Yadin David, in the
case styled In Re: Bair Hugger Forced
Air Warming Products Liability
Litigation, in the United States
District Court for the District of
Minnesota, MDL 15-2666.

The deposition today is being held at One Riverway, Suite 1400, Houston, Texas. Today's date is August 1st, 2017, and the time is approximately 9:17.

My name is Bob Birdsall, the legal video specialist, and the court reporter today is Susan Miller. We are both from TSG Reporting.

Would counsel please identify yourselves.

MR. BANKSTON: Mark Bankston on behalf of the Plaintiffs.

MR. HODGES: David Hodges on behalf of the Plaintiffs.

1 Y. DAVID
2 MS. EATON: Christin Eaton on
3 behalf of the Defendants.
4 MR. GOSS: Peter Goss on behalf of
5 the Defendants.
6 THE VIDEOGRAPHER: Thank you.
7 Court reporter, would you please
8 swear in the witness.
9 (Witness sworn by the reporter.)
10 P R O C E E D I N G S
11 YADIN DAVID, Ed.D., P.E., C.C.E.,
12 having taken an oath to tell the truth, the
13 whole truth, and nothing but the truth,
14 testified as follows:
15 EXAMINATION
16 BY MS. EATON:
17 Q. Good morning, Dr. David.
18 A. Good morning.
19 Q. Could you please tell us for the
20 record, what is your full name?
21 A. Yadin David.
22 Q. And what is your business address
23 at this time?
24 A. 1111 Hermann Drive, Houston, Texas
25 77004.

1 Y. DAVID
 2 Q. That is the address for what
 3 entity?
 4 A. For Biomedical Engineering
 5 Consultants LLC.
 6 Q. Do you understand that you're under
 7 oath today just as if you were in a courtroom
 8 or before a jury?
 9 A. I do.
 10 Q. When you answer my questions, will
 11 you use the standards and the rigor that you
 12 would use in your professional practice
 13 outside of a courtroom?
 14 A. I will.
 15 Q. You have been deposed before.
 16 A. Correct.
 17 Q. If you have any difficulty ever
 18 understanding my question or if you need
 19 clarification for my question, will you let me
 20 know, please?
 21 A. Yes.
 22 Q. Thank you.
 23 And if you ever need to take a
 24 break, as long as there's not a question
 25 pending, just let me know and we can do that.

1 Y. DAVID
 2 before today?
 3 A. Yes.
 4 Q. And did you make an effort -- did
 5 you read it?
 6 A. I did.
 7 Q. Do you know when you received it?
 8 A. I received it a few days ago.
 9 Q. Have you ever made an effort to
 10 compile information responsive to it?
 11 A. Yes.
 12 Q. When did you make that effort?
 13 A. Throughout my engagement with this
 14 case.
 15 Q. Since seeing the subpoena, have you
 16 made an effort to gather materials that would
 17 be responsive to it?
 18 A. I believe the material was already
 19 gathered.
 20 Q. Was that your impression when you
 21 read it?
 22 A. Yes.
 23 Q. Okay. When you read it a few days
 24 ago, did you discover anything that in your
 25 mind should have been provided or would be

1 Y. DAVID
 2 Okay?
 3 A. I appreciate that.
 4 Q. Thank you.
 5 I met you briefly this morning as
 6 you walked into the room. Had we ever spoken
 7 before that?
 8 A. No, we did not.
 9 Q. And have you ever spoken to anyone
 10 who you believe to be attorneys for 3M in the
 11 Bair Hugger litigation or for Arizant?
 12 A. Not as far as I know.
 13 Q. Is there any reason, because of
 14 medication, health or any other reason, why
 15 your testimony today can't be accurate and
 16 fair?
 17 A. No, there's none.
 18 Q. Okay. I would like to mark as
 19 Exhibit 1, or I have marked as Exhibit 1, a
 20 copy of the subpoena to you to produce
 21 information and document -- or to produce
 22 documents.
 23 (David Exhibit 1 marked.)
 24 BY MS. EATON:
 25 Q. Is this something you've seen

1 Y. DAVID
 2 responsive that wasn't already provided?
 3 A. No.
 4 Q. In what form did you believe the
 5 materials were already provided?
 6 A. In the basic fact that I gathered
 7 all the materials that I depended upon in
 8 binders, already there is no additional
 9 material that I can bring to the table.
 10 Q. Okay. How many binders of material
 11 did you have?
 12 A. I need to count. It's here in the
 13 box.
 14 Q. Oh, you have it here?
 15 A. Yes.
 16 Q. Okay. You have it in this room.
 17 Can you just point to the box so I can have a
 18 sense?
 19 A. Here it is.
 20 Q. Okay. One white box -- that one
 21 white box right there. Is that all the
 22 materials you've reviewed in connection with
 23 your work in this case?
 24 A. Correct.
 25 Q. Okay. Is it your understanding

1 Y. DAVID

2 that all of those materials are either cited
 3 in your report -- I'm sorry, let me separate
 4 that out.

5 Are there materials in that box
 6 that are not cited in your report or listed on
 7 the materials review list?

8 A. Everything is listed and cited one
 9 way or another.

10 Q. Okay. I'm going to go through it
 11 in a little more detail later, but for now, I
 12 just wanted to get that baseline.

13 Why did you obtain a Bair Hugger
 14 unit for purposes of your work in this case?

15 A. Sure. I wanted to acquaint myself
 16 with the product, with the way it is built,
 17 with its design, with the way that it is
 18 supposed to operate, and with the internal
 19 component that have Bair in this case.

20 Q. Had you ever seen a Bair Hugger
 21 device before you ordered the one from eBay
 22 that's described in your report?

23 A. I just want to correct one thing.
 24 I did not order myself. I asked counsel to
 25 order it for me.

1 Y. DAVID

2 Q. Thank you for that correction.
 3 A. And --
 4 Q. Before the device was obtained for
 5 purposes of your review that is described in
 6 your report, had you ever seen a Bair Hugger
 7 device before?

8 A. I did.

9 Q. Tell me about that.

10 A. I have been working for almost
 11 three decades in hospitals, and I recalled
 12 walking different areas of these hospitals,
 13 especially in the late '90s, that I've seen
 14 the Bair Hugger product used in patient rooms.

15 Q. Is that a specific memory of the
 16 late '90s as opposed to other time frames?

17 A. Correct.

18 Q. Did your profession -- okay. So
 19 you saw a Bair Hugger device in use in patient
 20 rooms.

21 What hospital or hospitals?

22 A. It would be difficult for me to
 23 pinpoint specific hospitals. I'll give you a
 24 list of a few of them that I worked at at the
 25 time that we are discussing here, and those

1 Y. DAVID

2 will be the St. Luke's Episcopal Hospital here
 3 in Houston and the Texas Children Hospital at
 4 the -- here in the Medical Center.

5 Q. In Houston also?

6 A. Correct.

7 Q. Okay. Those were the two hospitals
 8 you were working at at the time when you
 9 believe you saw a Bair Hugger device?

10 A. Correct.

11 Q. What was your responsibility at
 12 those two hospitals at that time, in the late
 13 1990s?

14 A. I was the director of the
 15 biomedical engineering department.

16 Q. What does that mean?

17 A. That means that I have the
 18 responsibility to make sure that medical
 19 technology used in these hospitals is
 20 selected, installed, maintained, and in
 21 service properly.

22 Q. You said "medical technology."
 23 What does that encompass?

24 A. In general, that will be biomedical
 25 devices.

1 Y. DAVID

2 Q. Can you give me an example of some
 3 biomedical devices?

4 A. Absolutely. Biomedical devices
 5 used for managing and diagnosing patient
 6 condition will be bedside monitors that --
 7 looking at patient vital signs. It will be
 8 X-ray machines, lasers in surgery. It will be
 9 blood-warming devices and laboratory
 10 diagnostic instruments.

11 Q. Is that a complete list?

12 A. Oh, my God, no.

13 Q. Okay. Those were examples?

14 A. I was responsible for about 25,000
 15 devices, biomedical devices, so we probably
 16 can spend the day going through the type of
 17 biomedical device on these assets.

18 Q. Would the Bair Hugger device be
 19 within the type of devices that you were
 20 responsible for?

21 A. I do not recall.

22 Q. You don't recall ever making an
 23 evaluation or decision about a Bair Hugger
 24 device?

25 A. Correct.

1 Y. DAVID

2 Q. Would it have been within the
 3 category of biomedical devices that you --
 4 would fall within the scope of your job?

5 A. Depends how it's arrived into that
 6 patient's room. If it was intended to be
 7 purchased, absolutely it would be my
 8 responsibility to review and evaluate. If it
 9 was on loan, rent, or brought by a third
 10 party, it will not be subjected to my
 11 evaluation.

12 Q. Do you know, at either St. Luke's
 13 or Texas Children's Hospital, if the device
 14 was purchased or brought in in some other way?

15 A. No, I do not.

16 Q. Is that distinction you've made
 17 about purchased versus brought in some other
 18 way something that would apply at both of the
 19 hospitals that you've listed, St. Luke's and
 20 Texas Children's?

21 A. Correct.

22 Q. Okay. Why do you -- are you saying
 23 there's a policy or procedure set out that
 24 that's how your responsibilities fall?

25 A. We did have many policies, and my

1 Y. DAVID

2 program was very well scripted and structured.
 3 There were a flexibility for especially the
 4 clinical staff to become aware of new
 5 technologies and use or review them on the
 6 loan basis or as a donation. That would be
 7 not subjected to evaluation.

8 Q. Did you say "clinical staff"?

9 A. I did.

10 Q. I wanted to make sure. At first I
 11 thought I heard the word "stuff" but I thought
 12 that you must have meant "staff."

13 A. I apologize for my accent, but I
 14 referred to people who were involved with
 15 clinical activities.

16 Q. Thank you. No need to apologize.
 17 I just wanted to be sure I understood you.

18 You're saying there was a policy of
 19 flexibility for clinical staff to use
 20 instruments that didn't come in through
 21 purchasing?

22 A. Correct.

23 Q. Was your role as biomedical
 24 engineer tied only to purchasing, then,
 25 devices purchased?

1 Y. DAVID

2 A. That's correct. My responsibility
 3 was to ensure that recommendations for
 4 commitment of hospital financial resources
 5 towards medical technology, i.e., biomedical
 6 devices, are based on several aspects that
 7 include the cost-benefit ratio analysis, risk
 8 analysis, and match between product feature
 9 and clinical needs, and that separate than
 10 trying to educate clinicians about new product
 11 or different product than they use.

12 MS. EATON: Can I just -- I just
 13 wanted to read one thing there, I'm
 14 sorry.

15 (Counsel reviewing realtime
 16 transcript on the reporter's computer.)

17 BY MS. EATON:

18 Q. I'm going to return to that history
 19 in a moment.

20 Had you ever -- but for now I want
 21 to return to the device that you evaluated for
 22 purposes of your work in this case.

23 Had you ever touched or used a Bair
 24 Hugger device before the one you obtained for
 25 your evaluation here?

1 Y. DAVID

2 A. Besides the one that I operated?

3 Q. I'm sorry, my question may not have
 4 been clear. For purposes of your work in this
 5 lawsuit and preparing the report that you
 6 prepared, did you obtain and review and
 7 operate a Bair Hugger device?

8 A. Correct.

9 Q. Other than -- how many Bair Hugger
 10 devices?

11 A. One.

12 Q. Other than that one, before you
 13 obtained that one, have you ever operated a
 14 Bair Hugger device before?

15 A. Not that I recall.

16 Q. Have you ever touched one before,
 17 in any way?

18 A. I cannot ascertain that. That does
 19 not ring a bell.

20 Q. You said you had a memory of having
 21 seen them in hospitals. Did you -- what is
 22 the -- can you tell me more about that memory?
 23 What do you recall?

24 A. No, I cannot.

25 Q. You recall having seen them and

1 Y. DAVID
2 that's it?

3 A. Correct.

4 Q. Okay. Do you recall having any
5 sense, at the time you saw them, for why they
6 were in an operating room?

7 A. I mentioned it was patient room. I
8 didn't say operating room.

9 Q. Oh, I'm sorry. Can you please
10 clarify for me, where did you see one?

11 A. I don't recall it. I don't believe
12 I was walking the operating room.

13 Q. What do you mean by "patient room"?

14 A. An area where a patient is being
15 observed on one of the general floors.

16 Q. Is this something before or after
17 surgery or not in connection with surgery at
18 all?

19 A. I have no recollection of that.

20 Q. Do you have any recollection of the
21 specific hardware -- in other words, what
22 model it would be, how large it was, how it
23 compares to the one that you obtained for use
24 in this case?

25 A. No.

1 Y. DAVID

2 evaluation or assessment about disposables
3 that are used with medical technology?

4 A. Yes, I did.

5 Q. Did you ever make any evaluation or
6 assessment about blankets used with the Bair
7 Hugger device?

8 A. I don't believe so.

9 Q. Did every piece of medical
10 technology that came into an operating room
11 become subject to an evaluation by your
12 department, if it was purchased?

13 A. My ego says answer that as a
14 positive yes so I can reflect on a very good
15 program. I would say the first time a type of
16 device is acquisitioned, probably it will be
17 evaluated. But if the same device is being
18 purchased years later and again and again, it
19 would not.

20 Q. Did you start the question -- I'm
21 sorry. Did you start your answer by saying
22 your ego would say yes because it was a good
23 program?

24 A. Yes.

25 Q. Okay. Meaning, in your mind, if

1 Y. DAVID

2 Q. Is this a specific memory of having
3 seen it one time, or do you believe you saw a
4 Bair Hugger device more than one time?

5 A. We are talking about something that
6 is about 20 years ago or more, so I cannot
7 differentiate if it's one or two times.
8 Definitely not something that would be
9 frequent.

10 Q. So with the clarification that you
11 saw it in a patient room, do you recall having
12 any understanding at the time you saw it about
13 why it was in the patient room?

14 A. No.

15 Q. Do you recall any discussion, ever,
16 during your work at a hospital, about Bair
17 Hugger devices and their use?

18 A. No.

19 Q. And I shouldn't have added those
20 last two words, because I meant it to be a
21 very broad question. Do you recall any
22 conversation during your time working in any
23 hospital about Bair Hugger devices?

24 A. No.

25 Q. Were you responsible for making any

1 Y. DAVID

2 you had a good program, you would want to have
3 looked at all the devices that were being
4 purchased?

5 MR. BANKSTON: Object to the form.
6 BY MS. EATON:

7 Q. Is that right?

8 A. The point to bring to this question
9 is that the process in the hospital is so
10 complex that there may be avenues that are not
11 main street but on the perimeter the device is
12 coming in through some kind of special
13 relationship with a vendor, and I would not
14 have the benefit of passing evaluation or
15 judgment on that.

16 Give an example, a blood analyzer
17 in the lab may have been purchased by buying
18 the agents that are used in the blood-drawing
19 process, the chemical agent. So as long as
20 the hospital buys those chemical agents, the
21 product is given to the hospital and there is
22 no evaluation involvement because there's no
23 purchasing of capital item. It's like the
24 Schick blade; you get the holder if you buy
25 the razor or something like that.

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1 Y. DAVID

2 Q. Within the terms of the programs
 3 at -- I'm sorry. Were you responsible for
 4 evaluating products at both Texas Children's
 5 and St. Luke's at certain times?

6 A. At certain times, correct.

7 Q. Within the program as you
 8 understand it at those hospitals, would the
 9 purchase of Bair Hugger blankets have brought
 10 the Bair Hugger device up for review by you,
 11 or not?

12 A. Now I'm hypothesizing with you
 13 about my response, because if you are telling
 14 me that there is requisition to buy a blanket,
 15 it sounds to me like the product is already in
 16 the hospital, so just add another accessory
 17 would not be subjected to evaluation.

18 Q. Do you know if Bair Hugger devices
 19 were purchased by either Texas Children's or
 20 St. Luke's Hospitals?

21 A. At the time that I was there, no, I
 22 don't know.

23 Q. Do you know if blankets were
 24 purchased?

25 A. No.

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1 Y. DAVID

2 specifically was to see device operation and
 3 the inside of the device after it was used in
 4 the field. So on purposely, I wanted to get a
 5 device that had some field experience with it.

6 Q. Why?

7 A. Because it gives me a view of what
 8 the device's capability to sustain its
 9 features in the field after it's been used for
 10 a period of hours. For example -- and I
 11 pointed that in my report -- is that I looked
 12 at the four feet on the bottom of the device
 13 and gave -- and realized that this device was
 14 used much on the floor because you could see
 15 the wear and tear on those four points at the
 16 base of the device.

17 So a device sitting on the floor
 18 has different performance on its enclosure
 19 than a device that would be up on the shelf or
 20 on an IV pole.

21 Q. What do you mean, it has a
 22 difference in the enclosure?

23 A. The performance of the
 24 characteristics of the physical enclosure, the
 25 box that covered the whole internal operation

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1 Y. DAVID

2 Q. You don't recall evaluating a Bair
 3 Hugger device -- and I apologize if I already
 4 asked you this. Do you recall ever evaluating
 5 the blankets?

6 A. I do not.

7 Q. Had you ever disassembled a Bair
 8 Hugger device before the work you did for this
 9 case?

10 A. No, I did not.

11 Q. And do you have any memory about
 12 the way the Bair Hugger device or devices you
 13 recall having seen in the past were being
 14 operated?

15 A. No, I do not.

16 Q. Why did you choose to examine a
 17 previously used Bair Hugger device for your
 18 work in this case?

19 A. Actually, this is a very good
 20 question. Because usually if you would like
 21 to review the device performance, especially
 22 in a clinical setting, you would like to have
 23 a new product that is fully capable to deliver
 24 all these features.

25 On the other hand, my goal

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1 Y. DAVID

2 and the components inside are subjected to
 3 specific wear and tear from floor, such as
 4 operating floors and recovery room floors.

5 Q. How does the floor and whether the
 6 device is placed on the floor or not impact
 7 the inside of the device, to your
 8 understanding?

9 A. There is a significant difference.
 10 A device that is placed on the floor is in
 11 closer proximity to an area that is not clean,
 12 that has higher concentration of pathogens,
 13 and that have more -- a higher percentage of
 14 relative humidity around the intake of the
 15 device. This gives rise to additional
 16 contamination of pathogens that the device can
 17 harbor.

18 Q. Okay. Did you examine a device
 19 that had been used and was not placed on the
 20 floor to see if the inside of the device
 21 looked any different?

22 A. Once again, I don't know where the
 23 device was used, but it's my observation that
 24 the bottom part of the device, the four feet,
 25 were subjected to significant wear and tear;

1 Y. DAVID
 2 therefore, it was moved about on a hard
 3 surface like a floor.
 4 Q. I'm sorry. My question was a bit
 5 different. Did you obtain any other used
 6 device that was not used on a floor to compare
 7 the insides of the two devices and see if they
 8 looked any different?
 9 A. I didn't see a need to do that.
 10 Q. Did you do it?
 11 A. If I didn't see a need to do it, I
 12 didn't do it.
 13 Q. Okay. Thank you.
 14 On what basis do you say that the
 15 inside of the device you examined looked any
 16 different than the inside of any other device
 17 that had been in use?
 18 A. I don't believe that I said that.
 19 Q. Well, I believe that you said you
 20 wanted to see an in-operation device and I
 21 believe that you said that the fact that the
 22 feet showed wear and tear was important to you
 23 because the inside would have a different
 24 environment. So maybe I should ask a
 25 different question.

1 Y. DAVID
 2 just as much information to you as the one
 3 that you examined?
 4 MR. BANKSTON: Object to the form.
 5 Object to the preamble.
 6 A. A new device would have a
 7 completely different purpose than what I was
 8 seeking. I wanted to see the device
 9 structure, how it would sustain its integrity
 10 of fitting the components together, how the
 11 filter fits into the device, where the air
 12 intake is, how close it is to a base that it's
 13 sitting on. So this was the particular reason
 14 that I wanted such a device.
 15 BY MS. EATON:
 16 Q. Did you know that you had available
 17 to you a new device?
 18 MR. BANKSTON: Object to the form.
 19 Misstates the record.
 20 A. I don't believe that I asked for a
 21 new device.
 22 BY MS. EATON:
 23 Q. Okay. What environment was the
 24 device that you obtained used in?
 25 A. I didn't receive that information.

1 Y. DAVID
 2 Do you believe that the operation
 3 of the Bair Hugger device you examined
 4 resulted in any difference in the inside of
 5 the compartment than would have occurred if
 6 the device had been operated in a different
 7 manner?
 8 MR. BANKSTON: Object to the form.
 9 Object to the preamble.
 10 A. I need to very simply clarify the
 11 purpose of my examination of the device. I
 12 wanted to see how the device is built, how
 13 it's put together, where the components
 14 physically sit, where is the intake, where is
 15 the output, how you connect the blanket to it,
 16 and I did not seek to make any performance
 17 comparison or derive any clinical outcome of
 18 the device use.
 19 BY MS. EATON:
 20 Q. When I asked you why you wanted a
 21 used device, you said you preferred one so
 22 that you could see its characteristics after
 23 use. Now that you describe the purpose here,
 24 let me ask a different question.
 25 Would a new device have provided

1 Y. DAVID
 2 Q. For how long had it been in use?
 3 A. The hour meter on the device
 4 indicated, as I had written in my report, over
 5 5,000 hours of use.
 6 Q. Do you know how typical that length
 7 of use is?
 8 A. No, I do not know.
 9 Q. Do you know how that length of use
 10 may have impacted the condition of the device
 11 that you had?
 12 A. The length of use will -- may or
 13 may not impact the device, and that's why I
 14 wanted to examine a used device, to see how
 15 well the filter mounting, for example,
 16 supports air flow, and to see can you clean
 17 the device, can you reach areas that can
 18 harbor bacteria or pathogens, and in general,
 19 to become -- to make myself acquainted with
 20 the product.
 21 Q. Did you see any issue with the
 22 filter mounting on the device that you
 23 examined?
 24 A. Not on that unit.
 25 Q. Did you see anything about the

1 Y. DAVID
 2 condition of the unit you examined that did
 3 not -- let me ask that differently.
 4 Did you see anything about the unit
 5 that you had examined that appeared to be a
 6 condition you thought had changed based on
 7 use?
 8 MR. BANKSTON: Object to the form.
 9 A. Can you clarify your question?
 10 BY MS. EATON:
 11 Q. Sure. You said you were looking to
 12 see how a device held up under use, roughly
 13 speaking. Is that right?
 14 A. Yes.
 15 Q. Did you see anything about the
 16 device you examined that you identified as
 17 something that might have been related to use,
 18 a condition that might have been related to
 19 use?
 20 A. I see.
 21 Sure. The obvious thing was lint,
 22 dirt, and accumulation of unclean particles.
 23 Q. Anything else?
 24 MR. BANKSTON: I object to the
 25 form.

1 Y. DAVID
 2 MS. EATON: What is the objection
 3 to that question?
 4 MR. BANKSTON: It calls for either
 5 a narrative or a complete accounting of
 6 everything that could possibly be
 7 different about the device.
 8 MS. EATON: Yes, it kind of does.
 9 I'm asking him for his expert opinion,
 10 and I think you're making too many
 11 objections here. That is not a valid
 12 objection.
 13 MR. HODGES: Object to the sidebar.
 14 BY MS. EATON:
 15 Q. Sir, did you identify anything else
 16 about the device that appeared to demonstrate
 17 a condition of use that was consistent with
 18 what you were looking for?
 19 A. There were several observations
 20 that I made. They are included in my report
 21 and very clearly indicate that upon turning
 22 the device on, connecting it to a power
 23 source, it went through the self-test, then
 24 identification of the device models and
 25 version of the software, and then I was able

1 Y. DAVID
 2 to see that there are fault codes, I think the
 3 abbreviation displays FC. And I mentioned
 4 that in my report.
 5 BY MS. EATON:
 6 Q. Were all the -- I'm going to get to
 7 your report in a minute, so we'll have that
 8 fault code in front of us.
 9 Was there a reason --
 10 MR. BANKSTON: Objection. Object
 11 to the preamble.
 12 BY MS. EATON:
 13 Q. Sir, I was just letting you know
 14 where I'm going so that you would understand.
 15 I will come back to the observations that are
 16 made in your report.
 17 MR. BANKSTON: And I'm going to
 18 object every time you don't ask a
 19 question. Object to the preamble.
 20 BY MS. EATON:
 21 Q. Was there a reason that you wanted
 22 a Model 750 specifically?
 23 A. As compared to what?
 24 Q. Any other model of Bair Hugger
 25 device?

1 Y. DAVID
 2 A. Since this is the product that I
 3 was asked to opine upon, that's the one I
 4 requested.
 5 (David Exhibit 2 marked.)
 6 BY MS. EATON:
 7 Q. I've marked as Exhibit 2 the
 8 response to the subpoena that was served in
 9 this case. Have you ever seen this?
 10 A. Not in this form.
 11 Q. If you would turn to the middle of
 12 this packet, there is an eBay -- a printout of
 13 an apparent eBay listing. It looks like this
 14 (indicating).
 15 A. Yes.
 16 Q. Did you go onto eBay and look for a
 17 device?
 18 MR. BANKSTON: Objection to form.
 19 A. I did not.
 20 MS. EATON: What's your objection
 21 to that question?
 22 MR. BANKSTON: Asked and answered.
 23 BY MS. EATON:
 24 Q. Do you know who did?
 25 A. Physically who did it, no. What I

1 Y. DAVID

2 know is that I requested counsel to provide me
 3 with exemplars, as we discussed earlier.

4 Q. What type of criteria, if any, did
 5 you request in terms of the device you wanted
 6 to see?

7 A. Very simply, a used device.

8 Q. Any other criteria you requested?

9 MR. BANKSTON: Objection to form.

10 A. No.

11 BY MS. EATON:

12 Q. Were you given more than one
 13 listing to review?

14 A. No.

15 Q. Were you given this listing
 16 contained in Exhibit 2 to review before the
 17 device was purchased to see if it met your
 18 criteria?

19 A. I don't believe so.

20 Q. Have you ever heard of Spectrum
 21 Surgical Solutions before?

22 A. No.

23 Q. In your work in hospitals, were
 24 refurbished or used medical technologies ever
 25 purchased?

1 Y. DAVID

2 A. The word "ever" called -- caught my
 3 attention. I would say, by far, all the
 4 acquisitions are of new products.

5 Q. Did you speak with anyone from
 6 Spectrum Surgical Solutions, Inc., about this
 7 device that you ultimately received?

8 A. No.

9 Q. And I should clarify for the
 10 record. If you turn to the page after the
 11 listing, there's reference to Spectrum
 12 Surgical Solutions in what I believe to be
 13 part of the eBay listing.

14 Do you know who provided the
 15 device?

16 A. No, I do not.

17 Q. Do you know if it was Spectrum --
 18 okay. So then you don't know who, okay.

19 Did you ever have any interaction
 20 with any company or person who you believe
 21 ever had possession of this device?

22 A. Ever have possession... since I
 23 don't know where it was used, I don't believe
 24 I can answer the question.

25 Q. You mentioned the fault codes. How

1 Y. DAVID

2 did you see those? Did you have to do
 3 something to get them to come up or did they
 4 just pop up?

5 A. No. You have to enter a mode
 6 specifically for query the archive of fault
 7 codes.

8 Q. Is that something that -- how did
 9 you -- sorry. Let me start with a new
 10 question.

11 Did you obtain a user's manual with
 12 this device?

13 A. I don't believe so.

14 Q. Or an operator's manual, anything
 15 like that?

16 A. No.

17 Q. How did you know how to query the
 18 archive, then?

19 A. I searched literature.

20 Q. What literature?

21 A. The literature that contained
 22 manuals, operation and service manuals, for
 23 this product.

24 Q. Where did you look?

25 A. I have -- first of all, I looked at

1 Y. DAVID

2 my own library. I have a library of manuals
 3 for different medical products, and then I
 4 went online and did search.

5 Q. What site did you ultimate- -- I'm
 6 sorry. I take it that because you went online
 7 it was not in your library. Is that a correct
 8 assumption?

9 A. That is correct.

10 Q. Do you know what site you
 11 ultimately found the manual from?

12 A. No.

13 Q. What did you find when you searched
 14 the archive for fault codes?

15 A. That there are many sources for
 16 such a document. And I looked at one that
 17 seemed to be comprehensive, and it has a PDF
 18 format of the manual, and I read it before I
 19 opened the shipping box of the device and
 20 realized that there is a way to identify a
 21 fault code by query the archive.

22 Q. Is the PDF you just mentioned
 23 something that is specifically cited or
 24 identified in your report?

25 A. I read it online. I never made a

1 Y. DAVID
 2 hard copy, and I don't believe that it is
 3 cited.
 4 Q. And you don't -- is there a
 5 particular search engine or search terms I
 6 could use to replicate and find the same one
 7 that you found?
 8 A. Easily.
 9 Q. Can you tell me those?
 10 A. You can go to Google and put "Bair
 11 Hugger Model 750 Manual" and you will get
 12 ample results.
 13 Q. But if I wanted to know which
 14 result you got, is there any further point you
 15 can give me?
 16 A. No.
 17 Q. Do you know what year the manual is
 18 for?
 19 A. I do not recall.
 20 Q. Okay. How many fault codes were
 21 there?
 22 A. Five.
 23 Q. Did you have -- what comes up? Is
 24 it a number, a word? When the fault code
 25 comes up, what comes up?

1 Y. DAVID
 2 A. It's a relatively small display of
 3 a few characters and it comes up with the
 4 capital letter F, capital letter C, brackets,
 5 with a number; and then I believe four digits.
 6 Q. Did you have any source to
 7 interpret what those fault codes meant?
 8 A. In the same manual, it had the
 9 codes.
 10 Q. What were the fault code numbers
 11 that came up?
 12 A. The three recent ones were code 50.
 13 The two prior to that, to make a complete
 14 total of five, were code 3 and code 8.
 15 Q. Did you make notes of that
 16 somewhere, what the codes were?
 17 A. No.
 18 Q. At the time you originally examined
 19 the device, did you make notes?
 20 A. No. My computer was with me and
 21 I -- after I read the manual, I opened the
 22 device under personal protection equipment and
 23 operated it and knew how to get to the code
 24 memory and look at that.
 25 You see, the simple fact is that I

1 Y. DAVID
 2 was not trying to have a device that simulated
 3 clinical utilization. My specific reason is
 4 to become familiar with the product integrity.
 5 So if I would have a device that I needed to
 6 do performance testing, I would set it up in a
 7 different environment than I used. I would
 8 have a protocol with specific tasks, and I
 9 will have a document showing the results.
 10 That was not my purpose.
 11 Q. Is that something you have done
 12 before, what you've just described, the
 13 performance testing?
 14 A. Sure.
 15 Q. Okay. In what role have you done
 16 that before?
 17 A. I'm doing that continuously for 40
 18 years, so I've done it as a biomedical
 19 engineer, I've done it as a research assistant
 20 in anesthesia, a dog lab. I've done that as
 21 director of biomedical engineering, and I'm
 22 doing it now as a consultant.
 23 Q. Is there one set of standards or
 24 criteria that you follow when you do that kind
 25 of performance testing, or does it vary by

1 Y. DAVID
 2 device?
 3 A. Sure, it's varied. That would be
 4 nice if all devices would have same feature
 5 and you can use one protocol, but as you well
 6 know, we -- on the street, we have trucks and
 7 we have cars and we have motorcycles and we
 8 have SUVs, and each one of them would be
 9 tested differently.
 10 Q. Is there an overarching approach
 11 that is documented that would apply to more
 12 than one device?
 13 A. Sure there is.
 14 Q. Can you give me that citation? Is
 15 it in writing, I should say?
 16 A. I don't know that there is a
 17 specific protocol so generic that you're
 18 asking about somewhere in the literature. I
 19 usually create my own protocol based on my
 20 education and experience and the device
 21 features.
 22 Q. When you do that, are you trying to
 23 reflect the clinical use condition for the
 24 device?
 25 A. It will be included.

1 Y. DAVID

2 Q. Why is that?

3 A. The purpose of a device is to have
4 impact on clinical outcome, so one would like
5 to know that there is a validation of the
6 product features and the clinical outcomes by
7 making tests that shows how well the two are
8 matched.9 Q. In doing that, is it important to
10 assemble the device as it will be used in the
11 clinical environment?12 A. First of all, if there is something
13 to be assembled, then the answer is yes. Not
14 always there is any assembly required.15 Q. When is the last time you looked at
16 the Bair Hugger device that was obtained from
17 eBay?18 A. Probably during the process of
19 writing my opinion report.

20 Q. Roughly, when would that be?

21 A. That would be March 2017.

22 Q. Do you have any notes of your
23 examination of that device other than what is
24 contained in your report?

25 A. No.

1 Y. DAVID

2 Q. You have carried the fault codes
3 just in memory?

4 A. Correct.

5 Q. Okay. Did you look up what they
6 meant, 3, 8 or 50?

7 A. At the time I did.

8 Q. Can you tell me, sitting here
9 today, what either code 3, code 8 or code 50
10 means?11 A. Code 50 was something about stuck
12 key during startup. I'm trying to recollect,
13 I'm not sure of that specific language, but
14 something to that effect.15 Code 3 and code 8, sorry, I don't
16 remember.17 Q. Is there -- I'm trying to have a
18 sense for the significance of those codes.
19 Was there anything about code 3 or code 8
20 that, to your view, would impact the
21 performance of the device?22 A. I think so. If I'm not mistaken,
23 code 8 or code 3 has something to do with the
24 heater. With the heater.

25 Q. Do you know what it had to do with

1 Y. DAVID

2 the heater?

3 A. I am afraid I can't recall.

4 Q. Was your only source of information
5 about what the code meant this operator manual
6 that you were looking at on the internet?

7 A. Yes.

8 Q. Did you do any other research to
9 determine whether that fault code might impact
10 the heating performance?11 A. I don't see a need for. I did not
12 seek clinical performance of the device as
13 part of my protocol.14 Q. Does that mean you did not do any
15 other research to determine whether that fault
16 code would actually impact the heating?17 A. In my experience as a biomedical
18 engineering expert, I understand or I
19 understood at the time the code to mean that
20 there is a problem with the heater, and since
21 I did not set my objective to determine the
22 performance of the device, I did not do any
23 additional investigation on the code.24 Q. Did you tell me that -- and I
25 apologize, I'm just not sure if I'm recalling

1 Y. DAVID

2 the timeline. Did you tell me that when you
3 first opened the device, took it out of the
4 box and turned it on, that's when you ran the
5 fault codes to see what they were?

6 A. No, I don't believe I said that.

7 Q. Do you recall when you ran the
8 fault codes?9 A. After I took the device to a
10 laboratory and put it together with a blanket
11 and operated it for the first time.12 Q. On the eBay listing on Exhibit 2,
13 there's a statement on the second page of the
14 listing. "Item removed" -- it's right
15 underneath the heading of what the unit is.
16 "Item removed from a working environment and
17 tested. All our equipment is tested,
18 certified" -- something looks to be maybe cut
19 off -- "with our biomedical technicians."20 Do you know what testing or
21 certification that would involve?

22 A. No, I do not.

23 Q. Have you ever bought equipment from
24 an eBay listing for use in one of the
25 hospitals that you were responsible for?

1 Y. DAVID
 2 A. Oh, no.
 3 Q. And have you ever instructed anyone
 4 else to do that?
 5 A. No.
 6 Q. Would you approve of it if someone
 7 else did?
 8 A. I don't think so, unless there is a
 9 life-and-death situation and that's the only
 10 solution.
 11 Q. You said something about the
 12 relative humidity and I wanted to be sure I
 13 understand what you were saying there. If I
 14 heard you correctly, you said that the
 15 relative humidity of a device while used on
 16 the floor would be greater.
 17 Did I hear that right?
 18 A. You did.
 19 Q. Okay. Can you please tell me what
 20 you mean by that?
 21 A. Sure. A device that is sitting
 22 about an inch, inch height from the floor, a
 23 floor that is subjected to cleaning agents and
 24 a variety of fluids, maybe fluids from
 25 patients, blood, et cetera, to have an air

1 Y. DAVID
 2 intake so close to such an environment that
 3 the humidity, the relative humidity that was
 4 in the product can be increased compared to
 5 other area.
 6 Q. Are you familiar with the various
 7 positions a Bair Hugger device may be used in
 8 in a hospital environment?
 9 A. Yes.
 10 Q. What are they?
 11 A. According to the intended use, it's
 12 everywhere there is a patient.
 13 Q. I'm sorry, my question may not have
 14 been clear. I was speaking about position on
 15 the floor versus position in some other way.
 16 Are you familiar with more than one potential
 17 way that a Bair Hugger device might be placed
 18 in an operating room?
 19 A. Yes.
 20 Q. What placements are you aware of?
 21 A. Well, this particular model, the
 22 750, has an IV clamp, and so I indicated in my
 23 report, and the purpose for this IV clamp is
 24 to place the product above the floor. So it
 25 could be on the IV clamp, it can be on the

1 Y. DAVID
 2 floor. For all practical purposes, you can
 3 put it on the meal tray next to the patient.
 4 So there is no limit, actually, to where it
 5 might be.
 6 Q. And it's your statement that the
 7 relative humidity within the device will be
 8 different depending on whether it's placed on
 9 the floor or an IV pole?
 10 A. Correct.
 11 Q. Have you ever measured the relative
 12 humidity inside the device in either location?
 13 A. No, I did not.
 14 Q. Have you ever measured the relative
 15 humidity of any air in an operating room?
 16 A. Absolutely.
 17 Q. In what conditions?
 18 A. As part of my responsibility for
 19 operating room safety and air pollution
 20 control and isolation power. In specifically
 21 operating room, I would be measuring relative
 22 humidity, temperature, and the status of the
 23 electrical isolation panels in the operating
 24 room.
 25 Q. Is there a standard for the

1 Y. DAVID
 2 relative humidity and what it should be kept
 3 within in an operating room?
 4 (Brief interruption.)
 5 A. Sorry. I thought that... it is on
 6 vibrate.
 7 MR. BANKSTON: That's weird.
 8 MR. GOSS: Then it's a loud
 9 vibration.
 10 THE WITNESS: Sorry about that, but
 11 it is on vibrate.
 12 Back to your question, the
 13 operating room has a range for standard
 14 environment for relative humidity and
 15 for temperature controlled by National
 16 Fire Protection Association, NFPA 1990
 17 standard, and by ASHRAE, American
 18 Society for Heating, Refrigeration and
 19 Air Conditioning, I think.
 20 BY MS. EATON:
 21 Q. Do you know what the humidity range
 22 is that's acceptable for an operating room?
 23 A. No, I'll have to search it.
 24 Q. And have you ever done any testing
 25 in an operating room that would demonstrate

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1 Y. DAVID

2 that the humidity reading by the floor is
 3 different from the humidity reading somewhere
 4 else?

5 A. I do not recall a specific study
 6 that I conducted about that. But since I was
 7 doing that frequently, I would change the
 8 altitude of -- or the height of the measuring
 9 device and it would show a higher humidity at
 10 the floor level.

11 Q. Can you tell me what any of the
 12 readings would be and give me a sense for how
 13 different one might be from the other?

14 A. No, I'm sorry. That was a very
 15 long time ago and very routine, almost weekly
 16 task, that I don't remember numbers.

17 Q. How long ago?

18 A. Probably late '70s, early '80s.

19 Q. And what kind of instrument were
 20 you using?

21 A. Hygrometer.

22 Q. Is the same type of instrument used
 23 today, do you know, as was used back then?

24 A. I believe so. It's very simple,
 25 taking a human hair and see how much it

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1 Y. DAVID

2 stretched in the presence of vapors.

3 Q. Okay. Are you able to give me any
 4 quantification at all of the difference at any
 5 height with -- either what the difference in
 6 height was, what the difference in temp- -- or
 7 humidity was, I'm sorry?

8 MR. BANKSTON: Objection, form.

9 A. I think we are marching towards an
 10 area of guessing. No, I cannot tell you. I
 11 can tell you simply that the device would be
 12 on the cart most of the time and sometimes I
 13 will take it and place it down on the floor
 14 just for my education.

15 BY MS. EATON:

16 Q. How high was the cart?

17 A. How high was the cart? I have no
 18 clue.

19 Q. Do you have any expertise in
 20 microbiology?

21 A. I do not.

22 Q. Do you think that the humidity of
 23 an environment makes a difference in the
 24 ability of bacteria to survive?

25 A. Yes, I do.

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1 Y. DAVID

2 Q. Based on what?

3 A. Based on studies that I read
 4 specifically for this case.

5 Q. Where will I find those in your
 6 report?

7 A. Oh, in many places. You can take
 8 Dr. Jarvis, a world expert in the area. You
 9 can take the microbiologist of 3M, Dr. Hall,
 10 specifically talking about it. There are
 11 ASHRAE standards that address that.

12 Q. I'll come back to that.

13 A. National Fire Protection
 14 Association, NFPA 1990, is another document.
 15 I was a member of that committee.

16 Q. When did you buy this -- when was
 17 this device purchased, do you know? I
 18 couldn't determine a year or a month on there.

19 A. I read here that it says delivery
 20 estimated between Monday, June 26 and Monday,
 21 July 10th.

22 Q. Yes, I did see that. I didn't know
 23 if you knew when it actually arrived or when
 24 you actually got it.

25 A. No, I don't remember.

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1 Y. DAVID

2 Q. You were retained in previous cases
 3 related to the Bair Hugger. Is that correct?

4 A. In singular, previous case, yes.

5 Q. You issued a report?

6 A. Yes.

7 Q. Did you ever examine a device
 8 before issuing that report?

9 A. I'll have to look at the report to
 10 refresh my memory.

11 Q. Do you have any memory of having
 12 examined a Bair Hugger device before this
 13 year, this -- the work that's reported in the
 14 report for this case?

15 A. I'll have to read that report, but
 16 as we sit here, no, I do not recall.

17 Q. If you would turn to Exhibit 2
 18 again for a moment, I see two invoices
 19 attached, and I believe that my copy reflects
 20 the invoices that we were provided for your
 21 work. If you could please take a look at
 22 those two invoices and see if you believe
 23 there are any others.

24 (Document review by witness.)

25 A. No, I think there is a -- a more

1 Y. DAVID
 2 recent one was just issued.
 3 BY MS. EATON:
 4 Q. When was it issued?
 5 A. Maybe 10 days ago, something like
 6 that, two weeks.
 7 Q. Do you have a copy of it available?
 8 A. No.
 9 MS. EATON: Counsel, can you
 10 provide that?
 11 MR. BANKSTON: Yeah, that's no
 12 problem.
 13 BY MS. EATON:
 14 Q. Does the issue that was just -- I'm
 15 sorry. Does the invoice issued 10 days or two
 16 weeks ago include your time -- all time from
 17 February 2017 through today?
 18 A. No.
 19 Q. Or through the time it was issued?
 20 I'm sorry.
 21 A. That's correct.
 22 Q. Okay. So those three invoices
 23 taken together will reflect your work on this
 24 case plus whatever has come since?
 25 A. That would be a true statement.

1 Y. DAVID
 2 Q. Do you have a sense for how many
 3 hours are on the invoice that was last issued?
 4 A. I was going to say about 30 hours.
 5 Q. Since that invoice was issued --
 6 I'm sorry, and what was that -- I apologize.
 7 What was that time spent on, just
 8 categorically, what kind of work?
 9 A. Basically preparation for
 10 deposition.
 11 Q. In the last 10 or 14 days since the
 12 close of the previous invoice, how much time
 13 have you spent?
 14 A. I did not review that.
 15 Q. I'm sorry, maybe we're not
 16 communicating.
 17 What was the time period that the
 18 last invoice closed with, what month or...
 19 A. I don't remember.
 20 Q. Okay. In July 2017, have you spent
 21 any time on this matter?
 22 A. Yes.
 23 Q. Is that included in any invoice?
 24 A. No.
 25 Q. Okay. How much time in July 2017

1 Y. DAVID
 2 have you spent?
 3 A. I didn't aggregate that.
 4 Q. Do you have any sense?
 5 A. No.
 6 Q. Did you spend any time preparing
 7 for this deposition in July 2017?
 8 A. Yes.
 9 Q. What did you do?
 10 A. I re-read depositions of other
 11 defendant officers, of other experts. I
 12 reviewed literature studies. I read my
 13 report. I read Mr. Ulatowski's report.
 14 That's about it.
 15 Q. What depositions did you review in
 16 July 2017?
 17 A. I believe I went over all of them.
 18 Q. All of the ones you had been
 19 provided?
 20 A. Yes.
 21 Q. You said something about experts.
 22 What expert depositions have you been
 23 provided?
 24 A. You want me to chant it from
 25 memory? It's in my report.

1 Y. DAVID
 2 Q. Okay. Let's go ahead and have your
 3 report in front of you. That's Exhibit 3.
 4 (David Exhibit 3 marked.)
 5 MS. EATON: Do you need a copy?
 6 MR. BANKSTON: Oh, no, I'm fine.
 7 BY MS. EATON:
 8 Q. If you would turn to page 46 of
 9 Exhibit 3 -- first of all, I'm sorry, sir, is
 10 Exhibit 3 your report? Does it appear to be?
 11 A. Yes.
 12 Q. And if you would look at page 45,
 13 is that your signature?
 14 A. Yes.
 15 Q. And page 46 begins a section titled
 16 "Materials Reviewed." Is that correct?
 17 A. That is correct.
 18 Q. And if I go through that, I don't
 19 see any expert depositions listed. Am I
 20 missing something?
 21 A. You're missing looking at page 49.
 22 Q. Okay. This is expert reports, and
 23 I'm sorry, I'm not interpreting that to mean
 24 depositions. Do you mean that you've read
 25 transcripts of depositions or have you read

1 Y. DAVID
 2 reports?
 3 A. Reports.
 4 Q. Have you read the transcript of the
 5 deposition of any expert witness for either
 6 plaintiffs or defendants?
 7 A. I think I read Mr. Tim -- I don't
 8 want to mispronounce his name --
 9 Q. Ulatowski?
 10 A. Thank you, Ulatowski.
 11 Q. His report or his deposition?
 12 A. I think his deposition.
 13 Q. Did you ever review his report?
 14 A. Yes.
 15 Q. Are there any other -- I don't
 16 believe that that's listed in your materials
 17 reviewed. Do you believe I'm mistaken about
 18 that?
 19 A. Everything I reviewed is in the box
 20 that I brought with me here, so if it's in the
 21 box, I reviewed it.
 22 Q. Okay. I'll take a look at that at
 23 a break.
 24 Do you believe that there are any
 25 other plaintiff or defense expert witness

1 Y. DAVID
 2 reports that are not listed on page 49 of your
 3 report that you have reviewed?
 4 A. No.
 5 Q. I'm just waiting for you to get
 6 there.
 7 A. No.
 8 Q. If you would look at page 46 of
 9 your report, there's some depositions listed.
 10 Did you read each of these depositions in
 11 total?
 12 A. Yes.
 13 Q. Okay. Any other depositions that
 14 you believe you've read beyond these listed
 15 and Mr. Ulatowski's?
 16 A. No. That would be it.
 17 Q. If we would look at Exhibit 2, I
 18 want to look at the invoices for a moment.
 19 Actually, first, I'm sorry, the
 20 very first item attached to this response is
 21 an expert witness retention contract. Within
 22 Exhibit 2, after the pleading part, there is
 23 an expert witness retention contract.
 24 A. Yes.
 25 Q. Is this your signature?

1 Y. DAVID
 2 A. Correct.
 3 Q. And is this related to the report
 4 that we have in front of us as Exhibit 3?
 5 A. Correct.
 6 Q. Okay. Dated October 15 of 2016?
 7 A. It does.
 8 Q. Was this when you were retained for
 9 your work in this case?
 10 A. I believe I was retained prior to
 11 that. I'm trying to think. We may not have
 12 that contract in place at the time.
 13 Q. If you would look at the first
 14 invoice, was the July 2016 meeting in person
 15 or by telephone?
 16 A. I do not recall.
 17 Q. Do you recall who you met with?
 18 A. No.
 19 Q. Do you recall if anyone was present
 20 that you did not believe to be an attorney?
 21 A. No. It's specifically a meeting
 22 with an attorney.
 23 Q. Who contacted you originally to
 24 retain you for Bair Hugger litigation in the
 25 first case?

1 Y. DAVID
 2 A. I believe Mr. Bankston.
 3 Q. Do you know Mr. Bankston from
 4 before that contact?
 5 A. We have a professional association
 6 on another case.
 7 Q. What case is that?
 8 A. It should be on my case list.
 9 Q. Are you able to point me to which
 10 one if you use Exhibit 3?
 11 (Document review by witness.)
 12 A. There's no list here.
 13 BY MS. EATON:
 14 Q. I believe between the report and
 15 your CV, tucked in there is a list. I don't
 16 think it's numbered by page or I would refer
 17 you to it.
 18 A. Oh, I see. On the second page, the
 19 fourth one from the top, Kaster, Lynch, Farrar
 20 & Ball, which is a light therapy.
 21 Q. Is that the only other time you
 22 have worked for a client that was represented
 23 by Mr. Bankston?
 24 A. Correct.
 25 Q. When did that -- 2014 is the year

1 Y. DAVID
2 listed here.

3 A. Yeah.

4 Q. Is that the year of testimony or
5 the year of all of your work?

6 Let me ask a better question. When
7 were you retained in that case?

8 A. It says 2014.

9 Q. That's -- your understanding is
10 that the year listed in this chart is the year
11 you were retained for a case?

12 A. The year that I provided
13 professional services.

14 Q. Did you prepare this list?

15 A. Yes.

16 Q. What is Biomedical Engineering
17 Consultants LLC?

18 A. This is a business that I'm
19 operated under.

20 Q. Are you the only person who works
21 in that business?

22 A. Correct.

23 Q. What do you do in that business,
24 other than -- I'm sorry, let me ask a
25 different question.

1 Y. DAVID

2 finally, I am -- develop and implement
3 telemedicine programs.

4 Q. For the regulatory advice that you
5 provide, is it advice about the -- I would
6 like more detail about that. What aspect of a
7 510(k) submission is it that you're advising
8 people about?

9 A. Sure. I'll be happy to help you
10 with that. The 510(k) submission has a
11 process that is looking for how to classify
12 the device, how to identify a predicate
13 device, what is the substantial equivalency
14 criteria that one can use, and specifically to
15 include studies and testing in a way that
16 supports the submission.

17 Q. What training or education did you
18 have that allows you to do that work, or that
19 you draw upon when you do that work?

20 A. Sure. I've been working in the
21 biomedical devices field for four decades and
22 use my expertise to understand how a device
23 works safely and what risk is associated with
24 them, seeing it from the clinical side.

25 I have obtained education and

1 Y. DAVID

2 Does that business involve any work
3 other than litigation consulting?

4 A. Yes.

5 Q. What else do you do?

6 A. I provide biomedical engineering
7 services to healthcare providers, meaning to
8 hospitals that would like to improve their
9 medical technology management program. I
10 provide professional services to manufacturers
11 of medical devices that would like to start or
12 improve their field biomedical services.

13 Q. Field?

14 A. Correct.

15 Q. Do you mean servicing devices in
16 the field?

17 A. Correct.

18 Q. Okay.

19 A. I provide regulatory services to
20 startup companies in the medical device field.

21 Q. What does that mean, "regulatory
22 services"?

23 A. Advise them on how to be ready for
24 510(k) submission and the appropriate
25 information to be included in such. And

1 Y. DAVID

2 finally, I am -- develop and implement
3 telemedicine programs.

4 Q. For the regulatory advice that you
5 provide, is it advice about the -- I would
6 like more detail about that. What aspect of a
7 510(k) submission is it that you're advising
8 people about?

9 A. Sure. I'll be happy to help you
10 with that. The 510(k) submission has a
11 process that is looking for how to classify
12 the device, how to identify a predicate
13 device, what is the substantial equivalency
14 criteria that one can use, and specifically to
15 include studies and testing in a way that
16 supports the submission.

17 Q. What training or education did you
18 have that allows you to do that work, or that
19 you draw upon when you do that work?

20 A. Sure. I've been working in the
21 biomedical devices field for four decades and
22 use my expertise to understand how a device
23 works safely and what risk is associated with
24 them, seeing it from the clinical side.

25 I have obtained education and

1 Y. DAVID

2 training throughout my career and have been
3 working with a consultant to the Food and Drug
4 Administration on several panels and have been
5 trained by the Food and Drug Administration to
6 fulfill that role. And I recently have been
7 asked to become a regulatory advisor to the
8 Innovation Institute of the Texas Medical
9 Center based on my experience and training.

10 Q. What regulatory training -- you
11 mentioned training, I think, regulatory
12 training. What regulatory training have you
13 had? Has it been part of any formal program
14 that you can identify?

15 A. At the master level when I was at
16 the university pursuing my degree, I took a
17 regulatory course that was taught by a
18 biomedical engineering professor. I continued
19 at the doctorate level to obtain training in
20 the field. I think it was a nurse who taught
21 the course at the doctorate level, but
22 regulatory principles. And I continuously
23 attend the annual meeting of biomedical
24 product and instrumentation and take a seminar
25 and lectures as well as reading books that are

1 Y. DAVID
 2 published as well as contributing to
 3 regulatory books myself. So I'm doing
 4 research to write my chapter for that.

5 Q. Okay. That's something ongoing
 6 right now?

7 A. No. That has been submitted,
 8 complete. The book has been published, I
 9 think end of last year.

10 Q. Is that on your CV?

11 A. Yes.

12 Q. Can you show me which one you're
 13 referring to? If you know the title off the
 14 top of your head, you can just tell me.

15 (Document review by witness.)

16 A. It looks like we don't have the
 17 recent year here on the copy I'm holding.

18 BY MS. EATON:

19 Q. Do you know the title of the book?

20 A. No.

21 Q. Are you able to provide me with an
 22 updated CV?

23 A. Sure.

24 Q. What was your chapter about?

25 A. I don't remember the title. It was

1 Y. DAVID
 2 about risk processes of medical devices
 3 subject to regulation.

4 Q. Of the regulation? What
 5 regulation?

6 A. Global medical device regulations.
 7 FDA, EU, others.

8 MR. BANKSTON: Is now a good time
 9 for a bathroom break? Should we do
 10 that?

11 MS. EATON: Sure.

12 THE VIDEOGRAPHER: We are going off
 13 the record at 10:42.

14 (Recess, 10:42 a.m. to 10:57 a.m.)

15 THE VIDEOGRAPHER: We are back on
 16 the record at 10:57.

17 BY MS. EATON:

18 Q. Dr. David, how many times have you
 19 met with attorneys that you understand to
 20 represent the plaintiffs in this Bair Hugger
 21 litigation, in person?

22 A. I don't keep count. Whatever is in
 23 my invoices, that would reflect it.

24 MS. EATON: And to be clear, I was
 25 hoping to get the remaining invoice

1 Y. DAVID
 2 before we're off the record today. I
 3 would like to receive it --

4 MR. BANKSTON: Yeah, sure.

5 MS. EATON: -- during the
 6 deposition.

7 BY MS. EATON:

8 Q. Every time that it says "meet with
 9 attorneys" here, is it a personal meeting?

10 A. Correct.

11 Q. Which attorneys have you personally
 12 met with, individuals?

13 A. I'm unable to rehearse that.

14 Q. Is there anyone whose name you
 15 recall that you met with?

16 A. Except those who are present here,
 17 no.

18 Q. Do you believe you have met with
 19 any other attorneys besides Mr. Bankston and
 20 Mr. Hodges?

21 A. Yes.

22 Q. How many other people?

23 A. I don't recall.

24 Q. Do you recall if they were men or
 25 women?

1 Y. DAVID

2 A. I believe they were men.

3 Q. Do you recall how many times you
 4 had a meeting where someone other than
 5 Mr. Bankston or Mr. Hodges was there?

6 A. No.

7 Q. Do you believe any of your meetings
 8 with attorneys also involved any people who
 9 you did not believe to be attorneys?

10 A. No.

11 Q. Did you meet with anyone to prepare
 12 for this deposition?

13 A. With Mr. Bankston.

14 Q. Just him?

15 A. Yeah.

16 Q. When was that?

17 A. That was yesterday.

18 Q. For how long did you meet?

19 A. Four hours.

20 Q. Any other meeting that you, in your
 21 mind, associate with preparing for the
 22 deposition?

23 A. No.

24 Q. Have you met with any attorneys
 25 since you prepared your report?

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1 Y. DAVID
 2 A. Can you repeat the question?
 3 Q. Have you met with any attorneys
 4 since you prepared your report?
 5 A. I meet with attorneys all the time.
 6 Q. Related to your work in this case.
 7 A. Mostly with Mark.
 8 Q. And have you met with him since you
 9 prepared your report, do you believe, other
 10 than yesterday?
 11 A. Yes.
 12 Q. Related to your work on the Bair
 13 Hugger litigation?
 14 A. Correct.
 15 Q. Do you recall how many times?
 16 A. No.
 17 Q. What percentage of the time of your
 18 business, Biomedical Engineering
 19 Consultants LLC, is spent on
 20 litigation-related work in the last five
 21 years?
 22 A. My business in totality has the
 23 activity we described earlier this morning.
 24 Q. Right.
 25 A. Which is more than the litigation,

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1 Y. DAVID
 2 and I don't keep separate accounts.
 3 Q. Do you have any sense? Is it more
 4 than 50% on litigation?
 5 A. I'll have to review five years of
 6 tax returns, but -- I don't know, might be
 7 correct.
 8 Q. Well, what about 2017? What
 9 percentage of your work activities in 2017
 10 have been related to litigation-related work?
 11 A. I don't believe, Counsel, that I
 12 keep separate revenue stream in separate
 13 accounts, so it's very difficult for me to
 14 answer your question. It will be just a
 15 guessing game.
 16 Q. Well, let me see if I can --
 17 what -- is your consulting rate the same --
 18 let me start over with a clean question.
 19 Is your consulting rate the same
 20 for any of the kinds of work that you do?
 21 A. Yeah. I might have different
 22 terms. For example, I am a consultant for a
 23 very known and large medical center in the
 24 Silicon Valley that required me to actually
 25 spend physical time there for a while, and my

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1 Y. DAVID
 2 rate was changed because the duration of the
 3 project was long. So, yes, the rate is
 4 changing.
 5 Q. Depending on the work?
 6 A. Correct.
 7 Q. Okay. Set aside revenue streams
 8 for a moment. I'm asking how you've spent
 9 your time in 2017. Do you have a sense for
 10 what percentage of the time you've spent in
 11 2017 has been related to litigation work?
 12 A. No.
 13 Q. More or less than 50%?
 14 A. I don't know.
 15 Q. Do you know if it's more than 75%?
 16 A. Definitely not.
 17 Q. For 2016, do you know if the amount
 18 of time that you spent on litigation-related
 19 work was more or less than 50%?
 20 A. That might be a good guess.
 21 Q. Well, I said more or less. Are you
 22 saying it's about half in 2016?
 23 MR. BANKSTON: I object to the
 24 form.
 25 A. I'm guessing. I don't know.

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1 Y. DAVID
 2 BY MS. EATON:
 3 Q. Do you believe it was more than 50%
 4 in 2016?
 5 A. I don't think so.
 6 Q. Do you believe it was more than
 7 25%?
 8 A. Now I'm guessing. So if you want
 9 me to guess, I would say more than 25%.
 10 Q. Well, I'm just asking for your best
 11 estimate of how you spent your time last year.
 12 MR. BANKSTON: Object to the form.
 13 A. I wish I could answer that. I do
 14 not keep booking records the way that you
 15 asked the question. My business in totality
 16 is what I enjoy doing, and those categories we
 17 described already have industry, academia,
 18 healthcare providers, litigation,
 19 telemedicine. I have both domestic and
 20 international projects in these categories.
 21 BY MS. EATON:
 22 Q. Has the amount of time -- I'm
 23 sorry. Has the percentage of time that you
 24 spend on litigation-related work changed over
 25 the last five years?

1 Y. DAVID
 2 A. It is changing year to year.
 3 Q. Has it been in a trendline of a
 4 certain direction, or does it vary?
 5 A. No. It just varies. It -- as I
 6 said, when I have a project like the Silicon
 7 Valley that would have long duration
 8 involvement with the medical center, naturally
 9 I'll have less time for other activities, so
 10 it's varied.
 11 Q. When was that project?
 12 A. That was 2016.
 13 Q. Are you able to identify the
 14 center?
 15 A. I'll have to see if I have any
 16 confidentiality agreement.
 17 Q. What was the work you were doing
 18 for that center?
 19 A. They are in the process of building
 20 adult and pediatric hospitals, new facilities,
 21 and wanted to make sure that they are ready,
 22 as far as their medical technology management
 23 program, for the challenge.
 24 Q. You're helping them to design their
 25 program or reviewing a program -- I'm sorry,

1 Y. DAVID
 2 let me -- what was your role in that?
 3 A. I reviewed the existing program and
 4 redesigned the program to meet the new
 5 challenges.
 6 Q. What posed the new challenges?
 7 A. As I said, the construction of two
 8 new facilities, the large amount of new
 9 technologies that would come to those
 10 facilities.
 11 Q. Was your focus on the process by
 12 which they review medical technologies?
 13 A. The process was part of it. Also,
 14 the ability to address deliverables as far as
 15 quantifying patient outcome relating to
 16 technology.
 17 Q. Was there a specific rubric or
 18 criteria for that addressing patient outcome?
 19 A. No. It depends on the environment.
 20 Outpatient clinic versus trauma versus
 21 pediatric floor.
 22 Q. I'm just wondering if there was a
 23 specific rubric that you used, a specific set
 24 of criteria or standards?
 25 MR. BANKSTON: Object to the form.

1 Y. DAVID
 2 A. The review was very elaborate, so
 3 yes, there was a certain criteria, but for the
 4 different steps there was different criterias.
 5 BY MS. EATON:
 6 Q. Did your work involve evaluating
 7 specific medical technologies?
 8 A. No.
 9 Q. For November 2016, if you would
 10 turn to the invoice in Exhibit 2, do you know
 11 how much of this eight hours was meeting with
 12 an attorney?
 13 A. Obviously it was less than eight
 14 because there are two other activities
 15 involved in that eight hours. How much less,
 16 I don't know.
 17 Q. Do you have a specific recollection
 18 that reviewing material and scientific
 19 literature is a separate task from meeting
 20 with the attorney?
 21 A. Yes.
 22 Q. Do you know what materials or
 23 literature you were reviewing in
 24 November 2016?
 25 A. No.

1 Y. DAVID
 2 Q. In December 2016, "Review material
 3 on-line vendors," what does that mean?
 4 A. That means that I search and review
 5 material associated with vendors with the use
 6 of computerized technology. I went online and
 7 looked at the information.
 8 Q. I don't -- what computerized
 9 technology? Vendors of what?
 10 A. Vendors of warming devices, patient
 11 warming devices.
 12 Q. Do you know what vendors you looked
 13 online for?
 14 A. No.
 15 Q. What was your purpose for looking
 16 at vendors of patient warming devices?
 17 A. To identify products that are
 18 offered on the market, to identify a spectrum
 19 of features, and any marketing material that
 20 they have.
 21 Q. Did you do the searching?
 22 A. Yes. I'm charging for my time,
 23 yes.
 24 Q. Well, you're charging
 25 specifically -- the entry says "Review

1 Y. DAVID
 2 material, online vendors," right?
 3 A. Yes.
 4 Q. Okay. Did you review material that
 5 was provided to you?
 6 A. No. Let me try to explain it so it
 7 will be clear. When I write on an invoice
 8 "Review material online," that means I went
 9 with search engines on the internet and looked
 10 at material. In this case, it says "vendors,"
 11 so I looked for vendors and products
 12 associated with heating patient technology.
 13 Q. What search engine did you use?
 14 A. I usually use the Google and the
 15 Firefox.
 16 Q. Do you recall which search terms
 17 you used to identify other patient warming
 18 devices?
 19 A. No.
 20 Q. Did you have any criteria for what
 21 kind of devices you were looking for?
 22 A. I probably have things in my mind
 23 and that's why I went to look to see if
 24 there's answers there. But as I sit here
 25 today, no, I cannot tell you words or key

1 Y. DAVID
 2 phrases that I put in.
 3 Q. Did you choose to examine materials
 4 for every patient warming device you located
 5 with this search?
 6 A. Correct.
 7 Q. Did you document in your report
 8 every patient warming device that you located
 9 with this search?
 10 A. No. I didn't see a need for that.
 11 Q. How did you select which ones you
 12 included in your report and which ones you did
 13 not?
 14 A. Those devices that have similar
 15 intended for use, devices that are marketed
 16 for similar environments of use, and devices
 17 that have a similar principle of conduction or
 18 convection heat. There are others that would
 19 have radiation heat, and I didn't use those.
 20 Q. Did you document in your report --
 21 okay, I'm sorry.
 22 You said you reviewed materials for
 23 all the ones that were located with your
 24 search and you documented in your report those
 25 that you considered relevant. Is that right?

1 Y. DAVID
 2 A. That would be a fair statement.
 3 Q. Do you recall which ones you saw
 4 and reviewed materials for and did not
 5 document in your report?
 6 A. There were -- an example will be
 7 infant warming devices that use infrared
 8 heating elements.
 9 Q. Okay. That would be radiant heat?
 10 A. Correct.
 11 There are forced-air devices used
 12 in a very specific environment like Isolette
 13 that I'm very familiar with, working at Texas
 14 Children's Hospital, did not include.
 15 Q. Anything else that comes to mind?
 16 A. No. Those are examples.
 17 Q. Did your search return the HotDog
 18 warming device?
 19 A. Sure.
 20 Q. Why is that not in your report?
 21 A. I picked up a similar device.
 22 Q. Why is the HotDog device not in
 23 your report?
 24 MR. BANKSTON: Object to the form.
 25 A. Because I took a similar device

1 Y. DAVID
 2 that used the same principle.
 3 BY MS. EATON:
 4 Q. Which --
 5 A. -- when -- and same features and
 6 put it in the list of devices.
 7 Q. Which device is that?
 8 A. I'll have to look at my report. I
 9 believe it's the VitaHEAT, V-I-T-A-H-E-A-T.
 10 And by the way, I see that on these invoices,
 11 the first entry is July 2016 and you asked me
 12 about the retainer agreement from October.
 13 And it shows you that I was working before
 14 that agreement was signed.
 15 Q. I didn't say that you were working.
 16 I had asked if you thought you were retained
 17 for the case before you began. Were you
 18 retained for the case during that initial
 19 meeting --
 20 A. Yes.
 21 Q. -- in July?
 22 A. Yes.
 23 Q. How many other warming devices had
 24 similar intended uses, marketed for similar
 25 environments of use, and a similar principle

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1 Y. DAVID
 2 of conduction or convection that you did not
 3 choose to include in your report?
 4 A. None.
 5 Q. The HotDog was the only one you
 6 left out?
 7 A. Yeah.
 8 Q. Did you look at materials about the
 9 HotDog?
 10 A. Yes.
 11 Q. What kinds of materials did you
 12 look at about the HotDog?
 13 A. I looked at the description, at the
 14 510(k) submission, at YouTube video.
 15 Q. How did you obtain the 510(k)
 16 submission for the HotDog?
 17 A. I think a summary document that was
 18 available online.
 19 Q. So you looked at the 510(k) summary
 20 or you looked at the entire 5- -- let me
 21 ask that differently.
 22 Do you believe that what you looked
 23 at was the entire 510(k) submission?
 24 A. I take your correction. Summary,
 25 yes.

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1 Y. DAVID
 2 Q. It was what was available online?
 3 A. Yes.
 4 Q. Do you -- did you -- I'm sorry.
 5 Did you print out any materials related to the
 6 HotDog?
 7 A. No.
 8 Q. Did you save any PDFs or download
 9 any materials related to the HotDog?
 10 A. I don't believe so.
 11 Q. Was the review of those materials,
 12 did that occur in December 2016 in connection
 13 with your review of other products?
 14 A. That would be a fair statement.
 15 Q. Will I find on your materials
 16 reviewed list any indication that you looked
 17 at materials about the HotDog? If you would
 18 look at Exhibit 3, I don't see anything, but I
 19 want to make sure that I'm not missing
 20 something.
 21 (Document review by witness.)
 22 A. No, I don't see a reference to it.
 23 BY MS. EATON:
 24 Q. Could you please turn specifically
 25 to page 46? I interpret pages 46 to 51 of

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1 Y. DAVID
 2 your report to be a listing of the materials
 3 you reviewed. Is that correct? In connection
 4 with your work in this case. Is that what
 5 this is?
 6 (Document review by witness.)
 7 A. Yes.
 8 BY MS. EATON:
 9 Q. Who prepared this list?
 10 A. Who prepared the list?
 11 Q. Yes.
 12 A. I did it. I don't think that I
 13 typed those numbers on page 47. That's --
 14 probably a clerk did it for me, but...
 15 Q. Are there other materials you
 16 reviewed in connection with your work in this
 17 case that we should add to this list?
 18 A. No.
 19 Q. Did you make an assessment that the
 20 VitaHEAT product and the HotDog product are
 21 the same?
 22 MR. BANKSTON: Object to the form.
 23 A. The same principle of warming
 24 patient, yes.
 25 --oOo--

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1 Y. DAVID
 2 BY MS. EATON:
 3 Q. Did you make a comparative
 4 assessment of their efficacy or safety?
 5 A. No.
 6 Q. In December 2016, there is a
 7 reference to FDA, just by itself. Do you know
 8 what that means?
 9 A. That means that continuing with the
 10 review material online. It was the vendor's
 11 website and FDA database.
 12 Q. For the 510(k) summaries?
 13 A. Yes.
 14 Q. Or for something else in addition?
 15 I'm sorry, that was a bad question. Was the
 16 only purpose for which you looked at the FDA
 17 website to obtain the 510(k) summaries on
 18 this?
 19 A. Yeah, I think so.
 20 Q. There's also an entry for "examine
 21 product."
 22 Does that mean the Bair Hugger
 23 device that you obtained for your work in this
 24 case?
 25 A. Correct.

1 Y. DAVID

2 Q. I'd like to talk about that
3 examination for a moment. There are entries
4 on December -- I'm sorry, in December 2016 for
5 "examine product."

6 In January 2017, there's a
7 reference to "device testing and photography,"
8 and in February 2017 there's a reference to
9 "device examination." I want to get a sense
10 for your work with the actual Bair Hugger
11 device. How many times did you do work,
12 review, inspection, testing, anything, with
13 that device related to your work in this case?

14 A. I believe the invoices are
15 reflecting correctly that I have activities in
16 December, January, February.

17 Q. Do you believe that when we receive
18 the next invoice, that will show continued
19 work with the product? Or do you believe this
20 was it?

21 A. I believe that's it.

22 Q. Exhibit 3 contains some photographs
23 of the device you examined, correct?

24 A. Correct.

25 Q. How many photographs did you take?

1 Y. DAVID

2 A. I don't have a list. I provided
3 the photography results to counsel and
4 incorporated in my report the one that I felt
5 would explain my opinions.

6 Q. Do you have any sense for how many
7 photographs you took?

8 A. No.

9 Q. Were they taken -- on what kind of
10 a device?

11 A. I believe it is a Pentax camera.

12 Q. Were they digital photographs?

13 A. Yes.

14 Q. Did you delete any of the digital
15 photographs you took?

16 A. No.

17 Q. Do you still have the original
18 media that the photographs were taken onto,
19 the chip?

20 A. I have the chip, but it was erased
21 and used for other purposes.

22 Q. So you don't have the original
23 photographs anymore?

24 MR. BANKSTON: Object to the form.

25 A. The original photographs would be

1 Y. DAVID

2 saved to my server, and then I used the chip
3 again.

4 BY MS. EATON:

5 Q. Okay. Do you have all of the
6 photographs you ever took of this device or in
7 connection with your work with this device on
8 the server?

9 A. Yes.

10 Q. Okay. On -- let's take a look at
11 the Exhibit 2. Actually, no, Exhibit 2 is not
12 going to help us.

13 (Sotto voce discussion.)

14 BY MS. EATON:

15 Q. I marked the subpoena as Exhibit 1.
16 Is that correct?

17 A. Yes.

18 Q. Let's take a look at Exhibit 1. If
19 we look at Exhibit A, the first entry asks for
20 documents reviewed in anticipation or
21 preparation for the deposition. Have you told
22 me earlier all of those that you can recall?

23 A. Yes, I did.

24 Q. The second item asks for
25 correspondence and deponent's exchange between

1 Y. DAVID

2 you and non-lawyers with information related
3 to your work in this case. Was there any such
4 correspondence or document exchange between
5 you and someone that was not a lawyer?

6 A. No.

7 Q. Category number 3, any notes
8 related to work in this matter, whether
9 handwritten or typed; are there any such
10 documents?

11 A. No.

12 Q. Category 4 are copies of documents
13 provided to you by plaintiffs' counsel on
14 which you have made notations, highlighting or
15 underlining. Have you brought all of those to
16 the room today with you?

17 A. Correct.

18 Q. Do you receive documents from --
19 have you received any documents from
20 plaintiffs' counsel?

21 A. Yes.

22 Q. Have you received those -- in what
23 format?

24 A. Hard copy.

25 Q. Have you ever received documents

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1 Y. DAVID
 2 electronically from plaintiffs' counsel?
 3 A. If I did, I requested hard copy.
 4 Q. The ones you reviewed came in hard
 5 copy?
 6 A. Correct.
 7 Q. Have you brought -- in this box
 8 that's sitting at my feet today, you've
 9 brought all the hard copies you received?
 10 A. Correct.
 11 Q. And if you made any notations or
 12 highlighting, I take it, then you would be
 13 making that on a hard copy as opposed to some
 14 electronic media?
 15 A. Correct.
 16 Q. Do you have a current impression
 17 about what items you may use as
 18 demonstrations, exhibits or aids in the course
 19 of your testimony?
 20 A. I have not discussed that with
 21 counsel, and I'm not aware that I'm providing
 22 testimony. He needs to advise me of that.
 23 Then I will think about what do I need to use.
 24 Q. If we look at category 6, does your
 25 CV, as of the time it was prepared, include

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1 Y. DAVID
 2 all of the books, treatises and articles that
 3 you have authored or co-authored up to that
 4 time?
 5 A. Correct.
 6 Q. Will you be able to provide me with
 7 a current CV that includes an update of
 8 everything that you've authored through now?
 9 A. Yes.
 10 Q. Do you have any written
 11 correspondence with anyone other than counsel
 12 related to your work in this case?
 13 A. No.
 14 Q. If you'd look at item number 17, do
 15 you have any written communications, including
 16 e-mails, between any of the individuals listed
 17 here?
 18 A. No, I do not.
 19 Q. Have you ever spoken with any of
 20 those people by telephone?
 21 A. I did not.
 22 Q. What about Scott Augustine? Have
 23 you ever spoken with him?
 24 A. No.
 25 Q. Have you ever exchanged any writing

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1 Y. DAVID
 2 with Scott Augustine?
 3 A. No.
 4 Q. Have you ever spoken with Randy
 5 Benham?
 6 A. Who is Randy Benham?
 7 Q. Well, first, let me ask if you
 8 recognize the name.
 9 A. I do not.
 10 Q. Okay. Randy Benham is an attorney
 11 at -- I believe he's an attorney for Scott
 12 Augustine or his entities.
 13 A. I see. No.
 14 Q. Does that context --
 15 A. No.
 16 Q. -- change your memory?
 17 A. No.
 18 Q. You don't believe you've ever
 19 exchanged writings with him?
 20 A. Correct.
 21 Q. Okay. In 20, there's a listing of
 22 some individuals who have the last name
 23 Augustine. Do you believe you've ever spoken
 24 to any of those people?
 25 A. None of those.

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1 Y. DAVID
 2 Q. Do you believe you've ever
 3 exchanged any communication with any of those
 4 people?
 5 A. No, I did not.
 6 Q. Okay. Item 21 asks for any study,
 7 test, trial, experiment, research or data
 8 that -- item 21 is a long question designed to
 9 get at any testing that you've done on a Bair
 10 Hugger device. I will use that shorthand for
 11 what actually appears in item 21.
 12 If you would look at the literal
 13 words of item 21 and please tell me if there's
 14 anything beyond what has been disclosed in
 15 your report that would fit that description.
 16 (Document review by witness.)
 17 A. No, nothing comes to mind.
 18 BY MS. EATON:
 19 Q. Do you have any documents
 20 responsive to category number 22?
 21 A. No, I don't have any of those.
 22 (David Exhibit 4 marked.)
 23 BY MS. EATON:
 24 Q. I've marked as Exhibit 4 a
 25 collection of additional photographs that were

1 Y. DAVID

2 not contained in your report. Well, I'm
3 sorry, let me say that differently.4 I requested that we receive any
5 photographs you had taken, whether or not they
6 were contained in your report, and I received
7 the items that are copied in Exhibit 4. Are
8 those photographs of the device that you
9 examined in connection for your work in this
10 case?

11 (Document review by witness.)

12 A. Yes.

13 BY MS. EATON:

14 Q. Did you take all of the photographs
15 that are in Exhibit 4?

16 A. Yes, I did.

17 Q. I counted 11. If you would,
18 please, double-check me.

19 A. Oh, they're two-sided.

20 Q. Yes.

21 A. I didn't know. You are correct.

22 Q. Do you believe that those 11
23 photographs, in addition to the ones that were
24 selected for your report, reflect all the
25 photographs you ever took of this device?

1 Y. DAVID

2 A. I believe so.

3 Q. Since receiving or reviewing the
4 subpoena that -- or actually, let me just ask
5 that differently. Would you be willing to
6 double-check your server to see for me if
7 there's any other photographs there that are
8 not contained in your report and in Exhibit 4?9 A. Will I have a copy of that to
10 compare?11 Q. Would you be willing to check your
12 server to see, yes, if Exhibit 4 and your
13 report contain all of the photographs that you
14 took?

15 A. Yes, I'm willing to do that.

16 Q. I would request that you do that
17 and inform your -- the plaintiffs' counsel if
18 there's anything that you find that is not
19 collected here. Is that something you could
20 do?21 A. Yes. The logistic issue is that I
22 need a copy of those to compare.23 Q. Sure. When we're done today, I can
24 give you my copy.

25 A. Okay.

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2 Q. You can take it with you.

3 Taking for a moment Exhibit 4 and
4 the photographs contained in Exhibit 4, had
5 you done anything to the device at all other
6 than take it out of the box and open it before
7 these photographs were taken?8 A. When you say "open it," I
9 disassembled. I mean, that's what you're
10 asking me?

11 Q. Yes.

12 A. I disassembled it.

13 Q. Yes.

14 A. Yes.

15 Q. Had you done anything else with the
16 device before you took the photographs?17 A. Probably wiped the outside. I
18 don't think much more than that.19 Q. Let me -- let's specifically go to
20 the fourth photograph. You know what? And
21 maybe -- would you take a moment and just use
22 a pen and write -- if you would write a 1 on
23 the first -- just in the little white spot on
24 the bottom of the first page of Exhibit 4 --
25 I'll do it at a break. I'll write pages. But

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2 if you could start with Exhibit -- or with
3 page number 1 of Exhibit 4.

4 A. Okay.

5 Q. Had you done anything to the device
6 at this time other than unscrew the cover and
7 remove it? Or the base, I'm sorry, the base,
8 and open it up to be able to take this
9 picture?10 A. Before I took this picture, I
11 probably removed the filter and then got to
12 the point where I'm taking this picture.13 Q. So by "the filter," do you mean the
14 corrugated rectangle that we see in the blue
15 base that's --

16 A. Correct.

17 Q. -- depicted here? You had already
18 taken the filter out and put it back in?

19 A. Correct.

20 Q. Is there any photograph, either in
21 your report or in this collection, that shows
22 the device before you took out the filter? Do
23 you know?24 A. The photographs in my report are
25 showing --

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1 Y. DAVID

2 Q. The one that shows you with the box
3 on page 11?

4 A. On page 11 and page 12.

5 Q. Okay. Who took the photograph on
6 page 11?

7 A. Myself.

8 Q. You took the photograph of
9 yourself?

10 A. Yes.

11 Q. How does that work?

12 A. You put it on timer.

13 Q. Was anyone present when you opened
14 the box and took the device out?15 A. No, I put it on a tripod with a
16 timer and took a picture.17 Q. I'm sorry. Separate from the issue
18 of the photograph, was anyone present when you
19 opened the box and took the device out besides
20 yourself?

21 A. No.

22 Q. Okay. And your belief is that the
23 photograph depicted on page 12 also is taken
24 right after you had taken the device out of
25 the box?

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2 A. Yes.

3 Q. Did you take that photograph -- any
4 other photographs here, in either your report
5 or Exhibit 4, that were taken during that
6 initial time when you opened the box, took the
7 device out, and before you had done anything
8 at all to the device?

9 A. No. That's it.

10 Q. If you look on page 12, when you
11 say, "When I opened the air intake and removed
12 the air filter," how would -- did you take off
13 the two screws that are depicted here in the
14 photograph on page 12 or is there something
15 else that you did?16 A. No. On the black part, the two
17 screws.18 Q. On the sort of rounded parts of
19 the -- the rounded parts of the black grate,
20 those screws that are apparent in the
21 photograph, you took those off?

22 A. The semicircle, yes.

23 Q. Okay. You said, "It was
24 immediately obvious that dust particles were
25 present on the filter and the blades of the

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2 fan behind it."

3 Is there any photograph depicting
4 what you saw when you first opened the air
5 intake?6 A. This series of photographs were
7 taken in sequence, so those are all -- come
8 after that.9 Q. Are you referring to the ones
10 contained in Exhibit 3 in your report, or are
11 you referring also to the ones in Exhibit 4?12 A. In my report, there are more than
13 on just that occasion. Like on page 14,
14 they're taken different time. But page 11,
15 12 --

16 Q. 13?

17 A. -- and 13 were taken the same time,
18 and then I think I came back and took what you
19 marked as Exhibit 4.20 Q. Okay. Let me be real clear just to
21 get this sorted out. 11, 12 and 13 you
22 believe were taken at the same time.

23 A. Correct.

24 Q. 14 was taken on a different day?

25 A. Correct.

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1 Y. DAVID

2 Q. What about the photographs that
3 appear on pages 15 and 16? Do you know if
4 those were taken --5 A. 15 and 16's were taken when
6 Exhibit 4 was -- the rest of the pictures in
7 Exhibit 4.8 Q. And is that a different occasion
9 than those on pages 11, 12 and 13?

10 A. Correct.

11 Q. Okay. Do -- let's go to the
12 photograph on the first page of Exhibit 4.
13 Does the filter in this photograph, was it
14 changed at all by your handling of it? Did
15 you do anything that would change the
16 appearance of the filter?

17 A. No.

18 Q. And then what about the motor and
19 blades that we can see on this page? Did
20 anything you do change the appearance of that?

21 A. No.

22 Q. Did you take any picture of the
23 filter as it appeared when you first opened
24 the cover? The base, I'm sorry, the base.

25 A. I do not recall.

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2 Q. Did you do any method of
 3 quantification of the dust particles that were
 4 present?

5 A. That was not my objective.

6 Q. Did you do any quantification of
 7 the dust particles that were present?

8 MR. BANKSTON: Objection to the
 9 form.

10 A. My objective for the examination
 11 was to understand the physical configuration
 12 and how the device integrated different
 13 components. I was not set to do a specific
 14 quantification of one parameter or another.

15 BY MS. EATON:

16 Q. I appreciate that information, sir,
 17 but I really -- and I can infer from your
 18 answer that you didn't do anything, but I
 19 actually do want a clear answer on the record
 20 so we are communicating.

21 Did you do anything to quantify the
 22 dust that you found?

23 MR. BANKSTON: Objection to form.

24 A. Besides visually look at it, no, I
 25 did not.

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1 Y. DAVID

2 BY MS. EATON:

3 Q. Did you take any sample and have it
 4 cultured to see what the dust was or what was
 5 in the dust?

6 A. Not my aim.

7 Q. And did you do it?

8 MR. BANKSTON: Object to the form.

9 A. I didn't see a reason to do it.

10 BY MS. EATON:

11 Q. Okay. I will infer from that
 12 answer that you didn't do it, and please
 13 correct me if I'm wrong about that.

14 MR. BANKSTON: Object to the form.

15 A. You're correct.

16 BY MS. EATON:

17 Q. Thank you. During your -- well,
 18 let me hold that for later.

19 Is there any photograph that would
 20 depict dust on the blades of the fan?

21 A. I don't think that I tried to
 22 document that.

23 Q. There's a reference on page 12 to a
 24 "dark and warm cavity." Did you actually take
 25 a temperature of the inside of the device at

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2 any time?

3 A. No, I did not.

4 Q. What do you mean by the word
 5 "warm"? What temperature range do you have in
 6 mind?

7 A. Higher than the surrounding
 8 environment.

9 Q. Do you have any knowledge from your
 10 work in this case about what is the
 11 temperature inside a Bair Hugger device when
 12 it is operating?

13 A. It will be above the room
 14 temperature because you have a
 15 magnificent-sized heating element sitting
 16 there and you can see the block of this
 17 electronic component in the center of the box.
 18 The enclosure is tightly around this heating
 19 element, so inside the box will be a higher
 20 temperature than in the surrounding room.

21 Q. And do you have any sense for what
 22 that temperature will actually be?

23 A. No.

24 Q. What does the photographs on
 25 page 14 depict?

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1 Y. DAVID

2 A. I believe that when I examined the
 3 device, that a layperson will not have a good
 4 comprehension of what does it mean for the
 5 principle of the device function that air
 6 needs to come from below the device and get
 7 into the heating element and push to the
 8 blanket around the surgical site.

9 So on page 14, I grossly simulated
 10 the function of air being vacuumed in or
 11 sucked into the enclosure by the function of
 12 the fan behind the filter. And those are the
 13 pictures explaining to a layperson. It's very
 14 simply if there is something next to the
 15 intake at the floor level, it will be sucked
 16 into the enclosure.

17 Q. Did you -- where -- if I look at
 18 the top picture on page 14, there's some
 19 scraps -- is this paper? Are these scraps of
 20 paper?

21 A. Correct.

22 Q. Did you set the Bair Hugger device
 23 down directly on top of those scraps of paper?

24 A. And so it said under the picture
 25 paper cuts are placed next to the bottom of

<p>1 Y. DAVID 2 the Bair Hugger side. So you can see that it 3 was placed just where the paper are sucked in 4 on the side of the enclosure. 5 Q. For purposes of the photograph 6 you've held the Bair Hugger in an elevated 7 position, right? 8 A. Correct. 9 Q. Okay. What I'm trying to figure 10 out is: When you actually turned it on, where 11 were the feet? 12 A. Sure, absolutely. The top picture 13 is showing you the elements involved in the 14 simulation; the Bair Hugger, the blue 15 enclosure on the left and the pieces of paper 16 cuts, white, on the right against black 17 background. Then I put the Bair Hugger over 18 those paper cuts, that they were such that I 19 could see from the side of the enclosure how 20 many of those are covered by the fan area and 21 turned the Bair Hugger unit on. Then I lifted 22 it and took a picture. 23 Q. Okay. So when you lowered the feet 24 of the Bair Hugger device, did the device sit 25 on top of any of the pieces of paper?</p>	<p>1 Y. DAVID 2 A. Yes. 3 Q. Did it sit on top of all the pieces 4 of paper? 5 A. No. The bottom picture is showing 6 you a piece of paper with the identification 7 of T2. 8 Q. Yes. 9 A. Those few pieces were at the 10 right-hand side in the top picture, those 11 three pieces of paper on the right side. So 12 the Bair Hugger was placed over the rest of 13 the papers. 14 Q. Are you able to take a pen, and on 15 Exhibit 3, outline roughly with either four 16 corners or a box which papers -- where the 17 device would have been sitting or which papers 18 were covered by the device? 19 A. Uh-huh. I'm going to mark it on 20 page 14. 21 Q. Yes, please. 22 A. But I don't want to confuse anybody 23 looking at it, that that's not where the Bair 24 Hugger was turned on. The papers were moved 25 on the white surface.</p>
<p>1 Y. DAVID 2 Q. Okay. I'm sorry, then. Back up. 3 When you turned the device on, where were the 4 papers? 5 A. On the white surface. 6 Q. Okay. When you turned the device 7 on, were the papers underneath the Bair Hugger 8 device? 9 A. In the same form you see it on the 10 black. 11 Q. Okay. So you took a picture on the 12 black and then you physically moved the papers 13 onto the white? 14 A. Correct. 15 Q. And then you set the Bair Hugger 16 back down on the white part on top of the 17 papers? 18 A. And as I said before, with the 19 three right-hand-side paper cuts outside the 20 filter area. 21 Q. Okay. Then no need to mark on 22 Exhibit 3 at this moment. 23 When you say "outside the filter 24 area," were those three paper marks by the T2, 25 the three pieces of paper, were they still</p>	<p>1 Y. DAVID 2 within the base of the Bair Hugger device, 3 beneath the base of the Bair Hugger device? 4 A. I think that I mentioned that I 5 could see it. 6 Q. Yeah. 7 A. When the device was on top of the 8 paper cuts, I could see those three outside. 9 Q. Okay. But within the white board 10 that is depicted here on page 14? 11 A. Correct. 12 Q. Okay. What setting did you turn 13 the Bair Hugger on to? 14 A. I used the three-temperature 15 setting, and for this particular picture, I 16 believe it was the high temperature. 17 Q. High temperature? Is there a 18 fan -- is there a different fan speed? Or is 19 there only one option for fan speed? 20 A. I'm aware of one option. 21 Q. Okay. Did you do anything to 22 measure the air flow? 23 A. No. 24 Q. Okay. What kind of a room was 25 this?</p>

<p>1 Y. DAVID</p> <p>2 A. This was a biomedical laboratory.</p> <p>3 Q. Okay. Is this laboratory designed</p> <p>4 to represent an operating room environment?</p> <p>5 A. I'm glad that you're asking this</p> <p>6 question, because once again, I want to make</p> <p>7 it clear that I did not attempt to look at the</p> <p>8 device performance or features. I did not</p> <p>9 need to simulate the environment where its</p> <p>10 function. Once again, I wanted to see and</p> <p>11 acquaint myself with the device operation and</p> <p>12 integration of different components and the</p> <p>13 air flow through it.</p> <p>14 Q. Was the laboratory designed to</p> <p>15 represent an operating room condition?</p> <p>16 MR. BANKSTON: Object to the form.</p> <p>17 A. I'm not that familiar with the lab,</p> <p>18 and I don't know if it was designed for it or</p> <p>19 not.</p> <p>20 BY MS. EATON:</p> <p>21 Q. Do you know if it did reflect</p> <p>22 operating room conditions?</p> <p>23 A. Probably did not.</p> <p>24 Q. Do you know anything about the air</p> <p>25 flow into the laboratory?</p>	<p>1 Y. DAVID</p> <p>2 A. No.</p> <p>3 Q. Do you know what the temperature</p> <p>4 was in the laboratory when you performed the</p> <p>5 operation that's depicted on page 14?</p> <p>6 A. Yes. I took the room temperature.</p> <p>7 Q. What was the room temperature?</p> <p>8 A. It was exactly as the</p> <p>9 air-conditioning scale showed, and it was</p> <p>10 74 degrees, I believe.</p> <p>11 Q. Fahrenheit?</p> <p>12 A. Correct.</p> <p>13 Q. Is that the temperature of an</p> <p>14 operating room during surgery?</p> <p>15 A. Probably not.</p> <p>16 Q. Did you intend for this exercise</p> <p>17 depicted on page 14 to represent the</p> <p>18 conditions during clinical use of a Bair</p> <p>19 Hugger device during a surgery?</p> <p>20 A. I might not be communicating</p> <p>21 clearly enough, so let me try again. My</p> <p>22 examination was not for clinical performance,</p> <p>23 was not intended on determining the features</p> <p>24 and the performance of the Bair Hugger 750 in</p> <p>25 a clinical environment or in an operating room</p>
<p>1 Y. DAVID</p> <p>2 or in any area that patients are cared for.</p> <p>3 My examination was specifically for</p> <p>4 acquainting myself with the product elements,</p> <p>5 with the physical characteristics of how it is</p> <p>6 functioning, and with understanding the</p> <p>7 relationship between air intake, air outtake,</p> <p>8 how the accessories are connected, and that's</p> <p>9 the extent of it. So we keep coming back to</p> <p>10 questions about operating temperatures and the</p> <p>11 lab that is designed to be operating room, and</p> <p>12 I want to make it clear that if I'm not</p> <p>13 communicating that issue, I will try it a</p> <p>14 different way.</p> <p>15 But it is a completely different</p> <p>16 purpose, and knowing that the device has</p> <p>17 multiple fault codes associated with it, it</p> <p>18 would be naïve to even try to do that features</p> <p>19 determination and clinical performance on such</p> <p>20 condition of the device. So it's further from</p> <p>21 my goals and objective as can be.</p> <p>22 Q. So if we were to show this</p> <p>23 photograph, for example, these photographs on</p> <p>24 page 14 to a lay jury, would it be important</p> <p>25 for them to have that in mind, all that you</p>	<p>1 Y. DAVID</p> <p>2 just said?</p> <p>3 A. Absolutely.</p> <p>4 Q. Did any of the pieces of paper get</p> <p>5 through the intake?</p> <p>6 A. No, they did not. The intake</p> <p>7 spaces of the levers -- I hope I'm identifying</p> <p>8 it correctly -- but the black cover over the</p> <p>9 filter has smaller gaps than the size of the</p> <p>10 paper and the paper cannot penetrate the</p> <p>11 plastic container that holds the filter in</p> <p>12 place.</p> <p>13 Q. So if we looked at page 12 of</p> <p>14 Exhibit 3, is that the grate that you're</p> <p>15 speaking about?</p> <p>16 A. Thank you. Very good. Yes.</p> <p>17 Q. Okay. So that grate was in place</p> <p>18 when -- was in place when the exercise was</p> <p>19 done that's depicted on page 14?</p> <p>20 A. Correct.</p> <p>21 Q. And all of the paper was stopped by</p> <p>22 it?</p> <p>23 A. Yes.</p> <p>24 Q. Did you ever do any test with a</p> <p>25 smaller-size particle than a sheet of paper?</p>

<p>1 Y. DAVID</p> <p>2 A. No.</p> <p>3 Q. Did you ever observe anything to move through the filter that you detected in some way?</p> <p>4 A. No, I did not.</p> <p>5 Q. Your report does use the word "suctioned."</p> <p>6 What's the definition of that term?</p> <p>7 A. To suck is bringing from --</p> <p>8 bringing an object from point A to point B by application of a vacuum. So in my report, what I use it for is to indicate that paper clips moved from one point to the other, actually raised from the table base towards the filter containing -- container by the vacuum that the fan is generating behind the filter.</p> <p>9 Q. When you said "clips," do you mean these pieces of paper or do you mean like a metal paperclip?</p> <p>10 A. You're right, I should have said cutouts.</p> <p>11 Q. It's what's depicted on page 14?</p> <p>12 A. Yes.</p>	<p>1 Y. DAVID</p> <p>2 Whenever you can let me have a break, that would be great.</p> <p>3 Q. That would be fine.</p> <p>4 THE VIDEOGRAPHER: We are going off the record at 12:05.</p> <p>5 (Recess, 12:05 p.m. to 12:18 p.m.)</p> <p>6 THE VIDEOGRAPHER: We are back on the record at 12:18.</p> <p>7 BY MS. EATON:</p> <p>8 Q. Do you -- sorry. Do you have any indication of how much suction would be required to remove a 10-micron particle from the floor?</p> <p>9 A. No, I do not.</p> <p>10 Q. And do you have any idea if the Bair Hugger device sitting on the floor could remove a 10-micron particle?</p> <p>11 A. Sure.</p> <p>12 Q. What's your idea?</p> <p>13 A. The idea that the heavier product, like paper cutout, would lift it easily.</p> <p>14 Q. That term "easily," is that a scientific term? Does it have a --</p> <p>15 MR. BANKSTON: Object to the form.</p>
<p>1 Y. DAVID</p> <p>2 BY MS. EATON:</p> <p>3 Q. -- any criteria or quantification you meant by that term?</p> <p>4 A. "Easily" is a term describing that there is no need to apply energy or force. And what I meant to say is that if a large number of fairly good-sized paper cutouts were lifted without much effort, that I would consider it to be easily done.</p> <p>5 Q. Okay. What kind of paper was the paper you used?</p> <p>6 A. It's a 20-pound white paper.</p> <p>7 Q. Okay. Do you have any idea what size microns these cutouts represent, how many microns they would reflect?</p> <p>8 A. Well, one can see the -- I'll use the word "easily" again, and easily calculate, because we know the size of a bacteria, for example, of 1- to 3-micron, which is a millionth of a millimeter, and I definitely can see that's much smaller than these 2-inches-wide paper.</p> <p>9 Q. That's actually a really good question. Do you still have the pieces of</p>	<p>1 Y. DAVID</p> <p>2 paper that were used and depicted on page 14?</p> <p>3 A. I believe so.</p> <p>4 Q. You do?</p> <p>5 A. Yes.</p> <p>6 Q. If you could provide those or somehow -- because I'd be interested, for example, in what size they are. Do you have measurements of what size they are?</p> <p>7 A. They are about 1-by-2 inches cut.</p> <p>8 Q. Is there a reason you chose that particular size?</p> <p>9 A. No.</p> <p>10 Q. Okay.</p> <p>11 A. And let me just make sure that I answer you correctly. I saw the piece of papers when I was working with the device back in December, January, February. I hope that I can find them.</p> <p>12 Q. If you are able to find them, I would ask you to keep them, and I'm not sure yet what exactly we would do in terms of an exchange or looking at them, but I would just ask that you look when you return to your lab -- do you still have access to the lab</p>

1 Y. DAVID

2 where you did this work?

3 A. Correct.

4 Q. Just look and see if you have them,
5 and if you would, I would ask that you keep
6 them.

7 A. Okay.

8 Q. So I take it from the answer you
9 gave me that the pieces of paper you used are
10 much larger than 10 microns.

11 A. Much larger, correct.

12 Q. You did not -- did I hear you
13 correctly that you did not attempt to suck
14 anything smaller than the pieces of paper
15 depicted on page 14 into a Bair Hugger device?

16 A. Correct.

17 Q. Do you have any basis for believing
18 that a Bair Hugger device could remove a
19 10-micron particle from the floor beyond the
20 work that is depicted on page 14?21 A. I believe that that exercise
22 demonstrated that there is sufficient force to
23 lift objects from the bottom of the feet of
24 the Bair Hugger towards the filter that's
25 about 1 -- less than 1 inches high.

1 Y. DAVID

2 device could lift any particular 10-micron
3 particle off the floor, correct?4 A. Correct. It's the concept of how
5 air is flowing into and out and what is being
6 condition internally at the Bair Hugger 750
7 with these components that I see; the filter,
8 the fan, the heating element, the electronic
9 control, the sensors of the temperature that
10 are put in the hose and how the blanket is
11 connected.12 Q. All of those things are why you --
13 what you were looking at?

14 A. Correct.

15 Q. Okay. Was there any active fault
16 code at the time that you turned on the Bair
17 Hugger device?

18 A. No.

19 Q. Other than the presence of the
20 historic fault code, did you have any reason
21 to believe that the Bair Hugger device was not
22 performing, at the time you looked at it, in
23 the same way that it was performing at
24 previous times?

25 A. To answer your question, I need to

1 Y. DAVID

2 Q. Was your purpose in doing the work
3 set out on page 14 to demonstrate that, that
4 the Bair Hugger device could lift things off
5 of the floor?6 A. The objective of my examination was
7 to understand how the Bair Hugger is
8 functioning, to familiarize myself with the
9 components and integral -- internal
10 integration of the different components and
11 how the accessories are tied into it, and the
12 understanding of how air is entering, getting
13 heated, controlled, and moved out of the unit
14 towards the blanket. That was my purpose of
15 the examination.16 The other question that's relating
17 to clinical performance or heating
18 quantification inside the box or outside the
19 box or lifting a specific object from the
20 floor were not part of my examination and were
21 never part of any attempt on my part to prove
22 something.23 Q. So the work that is depicted on
24 page 14, for example, would not, in your mind,
25 scientifically prove that the Bair Hugger

1 Y. DAVID

2 know how it was performing at previous time.
3 I have no knowledge how it was performing
4 previous time. It might have been defective
5 and abnormally behaving for quite some time
6 according to the fault codes that have many
7 hours of registration to them prior to me
8 handling it.9 But beside the point is that I
10 don't believe that I have any intention of
11 looking at performance.12 Q. Okay, yeah, I've heard that and
13 thank you. I just want to --14 MR. BANKSTON: I'm going to object
15 to you interrupting his answer. Let him
16 finish his answer. We've done that in
17 every deposition I've been with you, and
18 I've had witnesses go extremely -- let
19 the man finish his answer.

20 BY MS. EATON:

21 Q. Could we just -- I do understand
22 the purpose for which you've explained you
23 looked at the device. I just wanted to ask
24 something very specific on page 10 with
25 respect --

1 Y. DAVID

2 MR. BANKSTON: I object to the
3 form, that you didn't let him finish his
4 answer.

5 BY MS. EATON:

6 Q. There is a reference to the oldest
7 fault event occurring about 1939 hours
8 previous to the examination.

9 Do you see that?

10 A. Yes.

11 Q. And then there's another reference
12 to a second event occurring 447 hours previous
13 to the examination? Yes?

14 A. Yes.

15 Q. Okay. Did you get the hours --
16 does that appear along with the fault code on
17 the device?

18 A. Correct.

19 Q. Do you -- is there anything about
20 the way the fault code was displayed or any
21 information you were able to get from the
22 device based on your looking at the operator's
23 manual that would tell you if there had been
24 any repair done in response to that fault
25 code?

1 Y. DAVID

2 Q. And that's based on your review of
3 the operator's manual of what that fault code
4 meant?

5 A. Correct.

6 Q. If I push the device right now,
7 would I be able to access the archived codes
8 in the same way that you did, or has anything
9 changed about the way they would appear?10 A. The only change is due to memory
11 limitation and the archive of fault codes in
12 the device I believe limited to five. And if
13 there were additional fault codes occurring,
14 then it will drop the oldest one and will
15 enter the new one into its memory.16 Q. Do you know if any fault codes
17 occurred during your operation of the device?

18 A. I don't believe they did.

19 Q. You said, if I understood you
20 correctly, that when you checked the fault
21 codes was not when you first took the device
22 out of the box. Is that correct?

23 A. That --

24 Q. Yes? Go ahead.

25 A. That would be a correct estimate,

1 Y. DAVID

2 A. No. I cannot tell if it was
3 repaired or attended to.4 Q. You just made a statement, I think,
5 about maybe the device was defective for a
6 long time. Do you have any information
7 specifically you could tell me that the fault
8 codes you saw would mean the device was
9 operating in a way that you would call
10 defectively?11 A. Sure. If the fault code that I
12 remember seeing as number 8 and number 3 are
13 suggesting that the heater is not functioning
14 properly and it is a faulty condition, then it
15 is the basic functioning of the device to heat
16 and it's not doing it properly.17 Q. And is your basis for saying it's
18 not doing it properly your reading of what the
19 fault code meant or something else?20 A. I don't understand what it is,
21 "something else."22 Q. Is there something about the fault
23 code that you're saying means the device
24 wasn't heating properly?

25 A. Right. The fault code states that.

1 Y. DAVID

2 yeah.

3 Q. Do you recall if you tested the
4 fault codes -- I'm sorry, that's the wrong
5 word.6 Do you recall if you checked the
7 fault codes before or after the temperature
8 measurements that you took?

9 A. It was before I took measurements.

10 Q. For what purpose did you check the
11 fault codes?12 A. For no other reason, just to
13 understand the condition of the product.14 Q. Are the photographs in Exhibit 4
15 taken in connection with the time that you
16 took temperature measurements?

17 A. No. I believe that was after.

18 Q. Did you take any photographs in
19 connection with the time that -- I'm sorry.
20 When you took temperature measurements, was
21 that on the same day that you took the device
22 out of the box first?

23 A. No.

24 Q. Is there anything else you did on
25 the day that you took temperature

1 Y. DAVID
2 measurements?

3 A. I recall that I had to spend a
4 significant amount of time to get all the
5 shipping materials from the different spaces,
6 like in the hose and between the IV pole and
7 so on. There are a lot of...

8 Q. I am not understanding what you
9 mean. You mean you had to remove shipping
10 materials that had been placed in the device
11 for purposes of its shipment?

12 A. No, but --

13 Q. Okay. Then what did you mean?

14 A. If you look at page 11, you can
15 see -- I don't know what you call those white
16 particles inside the shipping box.

17 Q. Uh-huh.

18 A. And those were all over.

19 Q. Were they made of Styrofoam?

20 A. Yes. And they were getting into
21 all kind of nooks and cracks in the hose and
22 things like that. I remember that it took me
23 some time to clean all that. So that was the
24 things of getting it out of the box and
25 getting it ready for the next step.

1 Y. DAVID
2 box as the Bair Hugger device?

3 A. No.

4 Q. Do you know if the blanket came
5 from the same eBay vendor as the device came
6 from?

7 A. I do not know.

8 Q. Why did you request the device and
9 the blanket as a system?

10 A. If my aim is to understand how the
11 forced-air warming is taking aim at achieving
12 its purpose, I need to have all the components
13 connected together and the blanket has a
14 purpose of distributing heat over a surface
15 and maybe a secondary stage filter, I think.

16 But nevertheless, the blanket is
17 part of the device and I wanted to understand
18 how this system is integrated together, where
19 it's connected, what are the possibility of
20 air moving through the system, including
21 through the blanket, and how does it reach the
22 surgical site.

23 Q. Was the blanket that you used a --
24 designated somehow that you could perceive as
25 a Bair Hugger blanket, a use for -- a specific

1 Y. DAVID

2 Q. Was the unit itself encased in any
3 kind of a plastic bag, or was it just sitting
4 in these pellets?

5 A. I believe it was just sitting in
6 the pellets.

7 Q. Were there any pieces of Styrofoam
8 stuck within the louvers of the air intake
9 grate?

10 A. Yes.

11 Q. Had any pieces of Styrofoam moved
12 inside of the device?

13 A. If you call the hose the device,
14 then yes.

15 Q. What about between -- I'm sorry, on
16 the inside side, the in-compartment side of
17 the filter, was there any Styrofoam visible on
18 the inner compartment of the filter?

19 A. I see. Not that I remember.

20 Q. When you -- there's a reference in
21 here to a blanket. How did you obtain the
22 blanket that you used?

23 A. I requested the device and the
24 blanket, a system, from counsel.

25 Q. Did the blanket come in the same

1 Y. DAVID
2 box as the Bair Hugger device?

3 A. No.

4 Q. Do you know if the blanket came
5 from the same eBay vendor as the device came
6 from?

7 A. I do not know.

8 Q. Why did you request the device and
9 the blanket as a system?

10 A. If my aim is to understand how the
11 forced-air warming is taking aim at achieving
12 its purpose, I need to have all the components
13 connected together and the blanket has a
14 purpose of distributing heat over a surface
15 and maybe a secondary stage filter, I think.

16 But nevertheless, the blanket is
17 part of the device and I wanted to understand
18 how this system is integrated together, where
19 it's connected, what are the possibility of
20 air moving through the system, including
21 through the blanket, and how does it reach the
22 surgical site.

23 Q. Was the blanket that you used a --
24 designated somehow that you could perceive as
25 a Bair Hugger blanket, a use for -- a specific

1 Y. DAVID

2 blanket for use with the Bair Hugger device?

3 A. Yes. It has a casing, a flexible
4 plastic container, bag, that it has the Bair
5 Hugger name and a catalog number.

6 Q. Do you recall what number it was,
7 model -- what catalog or model number it was?

8 A. I probably still have it. No, I
9 don't remember.

10 Q. I would be interested in that. Do
11 you mean you have the blanket or the bag or
12 both?

13 A. I believe I have both.

14 Q. Okay. I would ask that you keep
15 those and I would -- again, I'm not sure what
16 the logistics of any transfer may be, but I
17 would be interested in that if you still have
18 it.

19 Do you recall what the blanket --
20 whether it would be -- do you recall how the
21 blanket matches up with any kind of
22 designation of upper body, lower body, under
23 body? And if you don't, just let me know,
24 but...

25 A. I don't recall the designation. I

<p>1 Y. DAVID 2 can tell you that it looks rectangular in 3 shape. 4 Q. Does it look like it would be the 5 full length of an adult body or less than the 6 full length of an adult body? 7 A. Less than the full length. 8 Q. Does it have any -- does it have 9 any pieces extending out to the side that you 10 might put over arms, for example? 11 A. No. 12 Q. Okay. Would it -- have you seen 13 any -- in any of the materials you reviewed, 14 have you seen illustrations of the different 15 kinds of blankets with designations of what 16 they are? 17 A. Yes. 18 Q. Do you have an idea of what kind of 19 blanket it was based on that review? 20 A. Not from memory. 21 Q. Do you think it would be for 22 placement on the abdomen or placement on the 23 legs? Any sense of that based on your review 24 of stuff? 25 A. Looks to me like the size of lower</p>	<p>1 Y. DAVID 2 body covering. 3 Q. When you -- was there more than one 4 time when you put the system together? 5 A. No. 6 Q. What space were you in when you put 7 it together? 8 A. In the lab. 9 Q. The same lab that is depicted on 10 page 14? 11 A. Correct. 12 Q. Where is that lab located? What 13 kind of -- is it your business' lab or a 14 university's lab? 15 A. No. It's a biomedical device 16 service lab that is in north part of town and 17 that I rent space when I need it. 18 Q. When you set up the system and took 19 temperature measurements, what was the blanket 20 sitting on? 21 A. The blanket was sitting on the 22 service bench. 23 Q. What's that constructed of? 24 A. Wood. 25 Q. Was it at the same height,</p>
<p>1 Y. DAVID 2 basically, as the unit, or higher or lower? 3 A. I would say about the same height. 4 Q. Was the temperature in the room 5 about 74 degrees at that time as well? 6 A. Correct. 7 Q. What instrument did you use to take 8 the temperature measurements? 9 A. It was a Fluke thermocouple 10 temperature monitor. 11 Q. Fluke? 12 A. F-L-U-K-E. 13 Q. I am not familiar with how a person 14 uses one of those. Could you please explain 15 for me? 16 A. Sure. It's a battery-operated 17 device that has connectors to sensors and a 18 display, digital display, with ranges. And 19 the device has been recently calibrated within 20 the last, I believe, 30 days of my use of it, 21 was calibrated to gold standard and have been 22 supplied with temperature probe. Those are 23 very similar to the microphone wires we see 24 here that are being used in this deposition on 25 each one of us.</p>	<p>1 Y. DAVID 2 Those microphone-like wires have a 3 thermocouple at the end. That's the name of 4 the device, thermocouple temperature 5 measurement, and the thermocouple, when it is 6 in environment either touching or in a 7 convection environment, the two metals that 8 perform this joint thermocouple is changing in 9 a different ratio and the monitor is able to 10 measure the resistance to electricity based on 11 the expansion of those pieces of metal. 12 That is very accurate temperature 13 monitor that's used in many research and 14 experiments, and I happened to have that 15 available to me when I rented the space. 16 Q. Were the perforations on the 17 blanket face-up or face-down when you did your 18 measurements? 19 A. The perforations were facing the 20 wooden block, facing down. 21 Q. Where did you place the Fluke 22 device in order to take the measurements? 23 A. So this thermocouple sensor, you 24 can imagine taking the tip, which is just this 25 microphone without the foam piece, and I taped</p>

1 Y. DAVID
 2 it underneath the blanket.
 3 Q. Was it just one thermocouple? I'm
 4 sorry, just one probe? Was it just one probe
 5 that you taped?
 6 A. No. I believe I had four.
 7 Q. Is it a standard method to use tape
 8 to attach it to a surface?
 9 A. It's a standard matter to attach
 10 thermocouple to a particular area that you
 11 want to measure. You can attach it with many
 12 different things. You can just lay it and
 13 hoping that the contact is sustained. You can
 14 tape it like I did. You can put glue and have
 15 it more permanent.
 16 Q. Does the tape -- I'm just trying to
 17 get a sense. Does the tape go over the back
 18 of the probe that's going to be measuring
 19 temperature or is there a way you can tape
 20 like a wire or something -- I know this is not
 21 a very artful question, but do you understand
 22 what I'm asking?
 23 A. Yes. And I think that I can
 24 illustrate to you and answer your question
 25 very clearly. If you look at the white tapes

1 Y. DAVID
 2 versus how much was laying flat on the bench?
 3 A. About 2 inches. The blanket was
 4 wider about 2 inches than the wooden block.
 5 Q. On each side?
 6 A. On one side.
 7 Q. Were the temperature probes between
 8 the blanket and the block or on the overhang?
 9 I'm sorry, that was a bad question.
 10 Were the temperature probes on the
 11 part of the -- beneath the part of the blanket
 12 that was laying flat on the block?
 13 A. Correct.
 14 Q. Okay. Were they out to the edges
 15 or were they in the middle? Where were they
 16 in connection with the blanket?
 17 A. I divided the blanket into four
 18 quarters and it was in each one of the
 19 quarters.
 20 Q. Was it in the middle of each
 21 quarter?
 22 A. I believe so.
 23 Q. Okay. Did you take notes of what
 24 the temperature measurements were?
 25 A. Except the average that is

1 Y. DAVID
 2 that is used here (indicating) to maintain the
 3 power cord on this table and you will take a
 4 portion, small portion of that, and I put it
 5 around the temperature probe. That's how it
 6 was attached.
 7 Q. Is there any reason to believe the
 8 presence of the tape would affect the
 9 temperature measurement?
 10 A. I don't see why. And once again, I
 11 did not aim at doing any temperature
 12 performance measurement as part of my
 13 examination, just to see what happened to the
 14 environment.
 15 Q. Where on the surface of the blanket
 16 were the -- so the probes you taped were
 17 beneath the blanket on the bench side if I
 18 heard you correctly. Is that right?
 19 A. That is right.
 20 Q. How wide was the bench compared to
 21 the blanket? Did the blanket hang over the
 22 sides?
 23 A. Yes.
 24 Q. Okay. Do you have a sense for how
 25 much of the blanket was laying over the sides

1 Y. DAVID
 2 mentioned in my report, no.
 3 Q. Did you write down the average
 4 that's mentioned in your report?
 5 A. That's what in the report is from,
 6 probably a note I took, at 36.
 7 Q. And I'm wondering, do you still
 8 have the notes that you took?
 9 A. No.
 10 Q. Do you believe that on the notes
 11 that you had you just wrote down that one
 12 number, 36, or did you write down several
 13 measurements that you then averaged to 36?
 14 A. The temperature ranges between the
 15 four quarters was insignificant so it didn't
 16 take much of a calculation to see the average.
 17 Q. Did you write down any individual
 18 data points in your notes?
 19 A. No. I think, one more time, I
 20 wanted to make sure that -- I'm not in a
 21 position to give you any reliable temperature
 22 quantification of that environment. It was a
 23 general concept of where it's heading, is it
 24 heating, is it cooling, is it doing anything
 25 to the blanket, and that's what I wanted to

1 Y. DAVID

2 see compared to the 74 degrees that we have on
 3 the AC thermometer.

4 Q. Sir, I asked you if you took any
 5 notes, and I'm wondering if in your notes that
 6 you took, you described for me, you took down
 7 individual data points or you only wrote the
 8 average. Are you able to tell me that?

9 A. I think that I did by telling you
 10 that the temperature range was all within
 11 decimal numbers, so there is no need to take
 12 numbers in average when they are about the
 13 same.

14 Q. I'm not asking what there's a need
 15 for. I'm asking what you did. Did you write
 16 down individual measurements?

17 MR. BANKSTON: Object to the form.

18 A. And as I responded to you, no. I
 19 took a review of the numbers and came up with
 20 the average. That's a sufficient estimate for
 21 my purpose.

22 BY MS. EATON:

23 Q. You've just said "decimals." Did
 24 every one of the four measurements begin with
 25 a 36?

1 Y. DAVID

2 looked at the device physical structure. I
 3 did not attempt to measure any clinical
 4 performance. I put temperature probes because
 5 I wanted to understand how the device is
 6 operating, not to determine if it is reaching
 7 specific clinical warming objective or not. I
 8 cannot give you a reliable temperature
 9 observation because that was not my aim, and
 10 what I saw was 36.0, 36.7, 36.9, variety of
 11 36-point-something that was easy to say that
 12 on the average they are 36.

13 BY MS. EATON:

14 Q. Are those numbers that you just
 15 said, 36.0, 6, 7, 9, are those specific
 16 memories or is that just a -- let me stop
 17 there.

18 Do you believe that those were
 19 specific readings you got?

20 A. No.

21 Q. Did you get any readings that were
 22 below 36 degrees?

23 A. I don't believe so.

24 Q. And you got some readings that were
 25 higher than 36 degrees but you can't be

1 Y. DAVID

2 A. Yeah.
 3 Q. Were any measurements higher than
 4 36 degrees?

5 A. Not that I recall.
 6 Q. They were all 36.0 degrees exactly?
 7 A. I believe you misrepresent my
 8 answer. I said there's no point. I didn't
 9 say they're all 36.0.

10 Q. I'm just trying to understand your
 11 answer and perhaps we're not communicating.
 12 Were there -- you've said in your report, if
 13 we look on your report on page 15, the last
 14 sentence of the first paragraph says, "When I
 15 measured several areas of a sample blanket,
 16 after 30 minutes of operation, I found an
 17 average temperature of 36 degrees."

18 I'm trying to understand what the
 19 individual measurements were that led to that
 20 average. Are you able to tell me?

21 MR. BANKSTON: Object to the
 22 preamble.

23 A. And that's perfect, because the
 24 sentence is exactly what I'm trying to
 25 communicate all day today, and that is I

1 Y. DAVID

2 precise about exactly how much higher?

3 A. Well, I think that I'm fairly
 4 precise. It's not the aim is to give you a
 5 reliable temperature reading, but what I'm
 6 telling you is that it's 36 and decimal
 7 changes. It's not 38, it's not 39. It's
 8 36-something.

9 Q. What about 37 degrees? Were any of
 10 the readings that you obtained 37 degrees or
 11 higher?

12 A. I don't recall that.

13 Q. I'm trying to figure out how
 14 numbers above 36 degrees averaged to
 15 36 degrees.

16 A. Very simply. I did not aim to
 17 scientifically monitor temperature feature of
 18 this device. I think we went over that
 19 multiple times today. I will do it one more
 20 time just to make sure that it's clear. It's
 21 not my aim to give you a reliable temperature
 22 quantification of what happened on this device
 23 with this blanket, so for me to report an
 24 average of 36 is sufficiently because the
 25 determination was that it's 36-point-something

1 Y. DAVID
 2 and I did not need scientific accuracy beyond
 3 the 36 whole number. I did not look for
 4 decimal fraction of a degree.

5 Q. How many temperature measurements
 6 did you take?

7 A. Excuse me, Counsel, I don't
 8 understand the question, how many temperature.

9 Q. There were four probes taped to the
 10 blanket, and how many times did you take a
 11 measurement from each probe?

12 A. Just like what my report is saying.
 13 I waited 30 minutes and let it stabilize and
 14 took a reading.

15 Q. Did you take a reading from each
 16 probe?

17 A. Mentally I did.

18 Q. You reviewed the results for each
 19 probe? You saw what the result was for each
 20 probe?

21 A. I'm not sure that your word of
 22 "result," but I showed the -- I saw the
 23 measurement of each probe, yes.

24 Q. At one point in time after the
 25 machine had stabilized for 30 minutes --

1 Y. DAVID

2 A. Correct.
 3 Q. -- did you look at the results --
 4 did you take any other measurements of
 5 temperature?

6 A. I think I said before, the room
 7 temperature.

8 Q. I'm sorry. From the probes that
 9 were taped to the blanket, other than this one
 10 observation, did you make any other
 11 observation of the temperature?

12 A. I see. No, I believe that's the
 13 totality.

14 Q. Did you take any photographs of
 15 that setup?

16 A. I don't believe so.

17 Q. Are you familiar with an ASTM
 18 testbed for warming blankets?

19 A. ASTM what?

20 Q. Are you familiar with the standard
 21 for testing the temperature related to a
 22 patient warming device in any respect?

23 A. I'm familiar with the ASTM
 24 organization, with their standards. I was a
 25 member of one of their committee, F-29,

1 Y. DAVID
 2 involved with anesthesia equipment at one
 3 time. I do not have specific recollection of
 4 what you're referring to as temperature
 5 measurement.

6 Q. There was a document included in...
 7 (David Exhibit 5 marked.)

8 BY MS. EATON:

9 Q. I believe you referenced -- I'm
 10 sorry, I didn't keep my copy. Let me just ask
 11 a different question.

12 I believe that this test report was
 13 contained within the materials you reviewed.
 14 Do you recognize it?

15 MR. BANKSTON: Object to the form.

16 BY MS. EATON:

17 Q. Do you recognize this document?
 18 (Document review by witness.)

19 A. Yeah, I believe I saw that with a
 20 color-coded graph.

21 BY MS. EATON:

22 Q. On the last page?

23 A. Yes.

24 Q. Do you know, if you look on the
 25 first page, what the ASTM F-29.01.10 fixture

1 Y. DAVID

2 is for testing convective warming blankets?

3 A. As we sit here, by heart, no. I'm
 4 familiar with ASTM. I'm familiar with the
 5 F-29 committee and the family of standards
 6 that they developed. It's very easy to obtain
 7 that material and to become educated about it.
 8 As we sit here today, no, I do not have that
 9 information.

10 Q. And I just want to be clear. Was
 11 the temperature measurement that you did
 12 related at all to the method, whatever it is,
 13 that would be described in this standard?

14 A. Well, the ASTM, and specifically
 15 the F-29 family of standards, are specifically
 16 set of standards that allow for product to
 17 comply with performance features. They can be
 18 a variety of features.

19 In this particular case it looks
 20 like the testing of a convective warming
 21 blanket. Since my purpose was nothing of the
 22 kind and has nothing to do with a review or
 23 establishing or disputing performance of a
 24 product and compare it to standard, my
 25 protocol in testing and temperature does not

1 Y. DAVID
 2 require to follow the ASTM F-29 fixture for
 3 testing.

4 Q. And I'm not saying it did. I was
 5 just trying to ask if there is anything -- and
 6 so let me start a clean question.

7 Was there anything about the test
 8 method you used that was designed to match or
 9 follow any ASTM guidance for testing
 10 convective warming air blankets?

11 A. Nothing that connected to my
 12 activity.

13 Q. If you had already seen the fault
 14 code before you did the temperature testing,
 15 why did you go ahead and do the temperature
 16 testing?

17 A. For the very simple reason that I
 18 wanted to see if the heating element is
 19 working at all, if the fan is functioning, and
 20 does the air flow through the whole system and
 21 out of the perforation in the blanket.

22 And the reason I made the
 23 measurement is to see if this is room air
 24 going through that is not being heated by the
 25 heating element or the heating element does

1 Y. DAVID
 2 contribute to the temperature change.

3 Q. What did you conclude based on your
 4 test?

5 A. Since the room temperature was much
 6 colder than a body temperature of 36 degrees
 7 centigrade, it was obvious that the heating
 8 element is contributing to warming the air as
 9 it's passing through the Bair Hugger device.

10 Q. On the date that you did the
 11 temperature testing, did you do any other
 12 thing with the device?

13 A. Sorry, I didn't hear you.

14 Q. On the day that you took the
 15 temperature test -- I'm sorry, let me start
 16 over.

17 On the day you took temperature
 18 measurements, did you do anything else with
 19 the device other than prepare it, which you
 20 have described?

21 A. I think we discussed the sucking
 22 force.

23 Q. That was on the same day?

24 A. Yes.

25 Q. With the pieces of paper.

1 Y. DAVID

2 A. Yes.

3 Q. Okay. Anything else?

4 A. No.

5 Q. Okay. Any other types of -- any
 6 other time you've ever operated the device
 7 except for that day? This device depicted in
 8 Exhibits 3 and 4.

9 A. Let me understand your question.
 10 You asked me if I ever operated the device
 11 other than on that day with the temperature
 12 probe?

13 Q. Correct.

14 A. The answer is yes.

15 Q. On how many other occasions did you
 16 operate the device?

17 A. I have no idea.

18 Q. Did you ever assemble the whole
 19 system, including the blanket, on any day
 20 other than that day?

21 A. Yes.

22 Q. Do you have any sense for how many
 23 occasions that was?

24 A. No. When I go to the lab, I want
 25 to make sure that I prepare, I have everything

1 Y. DAVID

2 that I need, and that the system is
 3 connectible and fully integrated. So I
 4 probably did it before I went to the lab.

5 Q. Any other observations you've made
 6 while operating the device that were relevant
 7 to you?

8 A. Other observations relating to the
 9 inability to clean the inside compartment of
 10 the device.

11 Q. That's based on your personal
 12 observation, you're saying?

13 A. Yes.

14 Q. Okay. What do you mean by that,
 15 "inability to clean"?

16 A. You need to have an engineer taking
 17 the product apart and disassemble it in order
 18 to get close to the compartment we see in the
 19 pictures, and yet it does not allow you entry
 20 into the heating element volume. So even if
 21 you have engineers that will take it apart,
 22 disassemble as I'm describing here, you might
 23 be able to get to the fan and the fan blades,
 24 but you won't be able to get to the rest of
 25 the air flow path through the heating element.

<p>Page 150</p> <p>1 Y. DAVID 2 Q. Do you know what the temperature is 3 inside the heating element? 4 A. Inside the heating element? No, I 5 don't. 6 Q. Is there any other area of the 7 inside of the device that one would not be 8 able to get to by doing what you did? 9 A. The enclosure, as we see in 10 page 15, separate into two large blue parts, 11 giving you an opportunity to understand that 12 there is a large vacuum spaces, empty spaces, 13 that they are subject to environmental 14 spoilage, and you cannot get to cleaning these 15 spaces unless you mechanically apply tools to 16 take those apart, and it's not recommended nor 17 suggested by anybody to do it. 18 Q. Why do you believe that the blanket 19 serves as a secondary filter? 20 A. Sorry? 21 Q. Why do you believe that the blanket 22 serves as a secondary filter? 23 MR. BANKSTON: Object to the form. 24 A. I believe it because I think I read 25 it in some of the material that is in my box.</p>	<p>Page 151</p> <p>1 Y. DAVID 2 BY MS. EATON: 3 Q. Did you do any testing or 4 measurement or observation related to that? 5 A. Observation, other than visualizing 6 that it does allow air to come up, no. 7 Q. Give me a second. 8 The day that we've been discussing 9 that's depicted on page 14 and includes the 10 temperature measurements, is that, do you 11 believe, in a month that is reflected in the 12 invoices we have, if you would look at 13 Exhibit 2? 14 A. So what is the question about 15 Exhibit 2? 16 Q. You know, actually you can look at 17 Exhibit 2 or not, but do you know when you 18 made the measurements? 19 A. No, I don't remember. 20 Q. Do you believe it would have been 21 in January 2017 when your description says 22 "device testing"?</p> <p>23 A. December 2016 is also examination, 24 examine product.</p> <p>25 Q. Right.</p>
<p>Page 152</p> <p>1 Y. DAVID 2 A. Oh, I see what you're saying, 3 "device testing." January 2017. Makes sense. 4 Q. Is there any other testing you did 5 on the device except what we've just been 6 discussing? 7 A. No. 8 Q. Do you believe that the testing 9 of -- with the paper cutouts and the 10 temperature measurements would have been done 11 in January 2017? 12 A. The best of my knowledge, I would 13 say yes. 14 Q. Was anyone else present when any of 15 that work was done? 16 A. No. 17 Q. Did you ever make any videos at any 18 time related to your work in this case, 19 anything that you did? 20 A. No. 21 THE WITNESS: Are we getting close 22 to lunch? 23 MS. EATON: Yes. Sure. Why don't 24 we go ahead and take lunch. 25 THE VIDEOGRAPHER: We are going off</p>	<p>Page 153</p> <p>1 Y. DAVID 2 the record at 13:13. 3 (Recess, 1:13 p.m. to 2:14 p.m.) 4 THE VIDEOGRAPHER: We are back on 5 the record at 14:14. 6 (David Exhibit 6 marked.) 7 BY MS. EATON: 8 Q. Hello. I have marked as Exhibit 6 9 a table of contents in one of the binders that 10 you brought today. It's titled "Other 11 Reference Materials." Is that correct? 12 A. That's correct. 13 Q. Did you -- how did you receive 14 those materials in Exhibit 6, reflected in 15 Exhibit 6? I'm sorry. 16 A. Those materials were put in the 17 binder based on how I structure my report. 18 Q. I'm sorry. Did you receive these 19 materials from someone or did you locate them 20 yourself? 21 A. It's a combination of me locating 22 and asking counsel to receive -- to obtain 23 those for me. 24 Q. Are there any documents listed on 25 the table of contents marked as Exhibit 6 that</p>

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1 Y. DAVID
 2 you yourself obtained?
 3 A. Sure. The ASHRAE standard I
 4 obtained myself. The Bair Hugger
 5 specification was provided to me. The CDC was
 6 provided to me. And the FDA, I put in.
 7 Q. You put in?
 8 A. Yep.
 9 Q. The table of contents refers to
 10 ASHRAE Standard 62.1, but what appears to be
 11 behind the tab is a series of PowerPoints and
 12 an M.D. Anderson Cancer Center document.
 13 Do you know why that is?
 14 A. Yeah. The M.D. Anderson document
 15 is an institutional policy relating to how
 16 standards should apply to the construction of
 17 personal protective environment in similar
 18 spaces and using the standard that ASHRAE has
 19 structured. So it is under A.
 20 And under B is the Canfield merit
 21 rating and filter designation based on the
 22 ASHRAE standard as well, so it's under the
 23 ASHRAE standard as support material.
 24 Q. And are you thinking that both of
 25 those items you've just talked about relate to

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1 Y. DAVID
 2 ASHRAE Standard 62?
 3 A. To ASHRAE Standard 62, yes.
 4 Q. You were looking at the front page
 5 of a PowerPoint there when you said that?
 6 A. Correct.
 7 Q. And how did you obtain that
 8 PowerPoint?
 9 A. This is online. Search online.
 10 Q. Okay. You were -- did you look at
 11 the actual ASHRAE Standard 62?
 12 MR. BANKSTON: Object to the form.
 13 A. No, I don't believe so.
 14 BY MS. EATON:
 15 Q. Do you know what ASHRAE Standard 62
 16 is?
 17 A. It's indoor ventilation.
 18 Q. Does it apply to hospitals?
 19 A. It's included, healthcare
 20 facilities.
 21 Q. Do you have familiarity with the
 22 standards in general that apply to hospital
 23 settings or hospital operating room settings?
 24 A. In general, I do, yes.
 25 Q. Have you worked with ASHRAE

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1 Y. DAVID
 2 Standard 62 before?
 3 A. "Worked with" is a large area of
 4 involvement. I have used those kind of
 5 standards in my line of work.
 6 Q. Have you used that specific
 7 standard in your line of work?
 8 A. Yes.
 9 Q. ASHRAE Standard 62?
 10 A. Yes.
 11 Q. Okay. I may come back to that if
 12 there's time.
 13 (David Exhibit 7 marked.)
 14 BY MS. EATON:
 15 Q. Deposition Exhibit 7, I've marked
 16 the entire notebook, including the table of
 17 contents. Is this the material that you refer
 18 to in your materials reviewed list concerning
 19 other products?
 20 A. That would be correct.
 21 Q. Was it your understanding that that
 22 material was provided to me before today?
 23 A. Material provided to you? I don't
 24 understand the question.
 25 Q. Do you have any belief that that

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1 Y. DAVID
 2 material was provided to me, to counsel for
 3 3M, before today?
 4 MR. BANKSTON: Object to the form.
 5 A. I don't know.
 6 BY MS. EATON:
 7 Q. Is that information that you
 8 reviewed in coming to your opinions?
 9 A. Yes.
 10 Q. Okay. And is that the information
 11 that you pulled off the internet that you were
 12 talking about this morning?
 13 A. Not necessarily internet.
 14 Q. From where did you obtain that
 15 information if not the internet?
 16 A. Well, I asked counsel about the
 17 510(k)s, I didn't find those. It's a
 18 combination between me finding it and asking
 19 counsel to provide me.
 20 Q. Okay. So if you would open that
 21 notebook again and look at the table of
 22 contents, there are several 510(k) summaries.
 23 Is that correct? As opposed to full 510(k)s?
 24 A. Yes, I see a couple of summaries.
 25 Q. You're saying the summaries of

<p>1 Y. DAVID</p> <p>2 510(k)s you were not able to get off of the</p> <p>3 internet?</p> <p>4 A. No, I said the full 510(k)s.</p> <p>5 Q. Well, I don't see any full 510(k)s</p> <p>6 in that document. Have I missed that? I'm</p> <p>7 sorry. I said "document." I mean notebook.</p> <p>8 Is it your belief that you reviewed</p> <p>9 any full 510(k)s for any other non-3M,</p> <p>10 non-Bair Hugger products?</p> <p>11 A. I think I don't remember exactly,</p> <p>12 but this might be one that I did not find, the</p> <p>13 VitaHEAT.</p> <p>14 Q. Okay. So you believe that one may</p> <p>15 have been provided by counsel?</p> <p>16 A. Probably. Probably.</p> <p>17 Q. And the other materials that are in</p> <p>18 that book, did you find all of them?</p> <p>19 A. I think so, yeah. I don't</p> <p>20 necessarily recall one way or the other, but I</p> <p>21 know that I know how to get them.</p> <p>22 Q. With respect to the materials that</p> <p>23 you reviewed about other products in</p> <p>24 connection with coming to your opinions in</p> <p>25 this case, is there anything outside of what's</p>	<p>1 Y. DAVID</p> <p>2 contained in Exhibit 7 and what we discussed</p> <p>3 this morning with respect to the HotDog?</p> <p>4 A. That would be it.</p> <p>5 Q. Okay. Did you actually examine any</p> <p>6 of the devices that are reflected in Exhibit 7</p> <p>7 or the HotDog in connection with your work in</p> <p>8 this case?</p> <p>9 A. No.</p> <p>10 Q. Have you ever, in your</p> <p>11 professional -- have you ever -- I'm sorry,</p> <p>12 let me start over with a clean question.</p> <p>13 Have you ever reviewed any of the</p> <p>14 devices that are listed on the table of</p> <p>15 contents for Exhibit 7, ever seen them,</p> <p>16 examined them?</p> <p>17 A. That's why I'm looking at the CSZ</p> <p>18 because I think that I saw that before.</p> <p>19 Q. You might have seen that --</p> <p>20 A. Yeah.</p> <p>21 Q. -- in a hospital?</p> <p>22 A. Yeah.</p> <p>23 Q. Did you ever examine it for</p> <p>24 purposes of seeing how it was operated or --</p> <p>25 A. Yeah. This was not in a hospital.</p>
<p>1 Y. DAVID</p> <p>2 It was in outpatient.</p> <p>3 Q. Okay. And what -- did you do</p> <p>4 anything other than just see it?</p> <p>5 A. Right. I was in that environment</p> <p>6 for a different reason.</p> <p>7 Q. Is it fair to say that all you did</p> <p>8 was simply see it in an outpatient</p> <p>9 environment?</p> <p>10 A. Correct.</p> <p>11 Q. Did you make any kind of</p> <p>12 examination or test of that device?</p> <p>13 A. No.</p> <p>14 Q. Have you ever evaluated any of the</p> <p>15 devices listed on the table of contents for</p> <p>16 Exhibit 7 in the course of your professional</p> <p>17 work?</p> <p>18 A. Besides through the literature that</p> <p>19 is here, no.</p> <p>20 Q. In the course of your work outside</p> <p>21 of this lawsuit, have you ever evaluated any</p> <p>22 of those devices for a hospital application?</p> <p>23 A. I see. No.</p> <p>24 Q. I do not believe that we ever</p> <p>25 received those materials before today, and I</p>	<p>1 Y. DAVID</p> <p>2 have not had time to really look through them.</p> <p>3 MR. BANKSTON: That would be</p> <p>4 surprising to me because I was</p> <p>5 specifically asked to get them and pass</p> <p>6 that along. So I don't know if in that</p> <p>7 chain it didn't make it, but it would be</p> <p>8 surprising to me because you have the</p> <p>9 pictures and they were with the pictures</p> <p>10 so that's somewhat surprising to me.</p> <p>11 But if it's not, it's not. I don't know</p> <p>12 what to tell you.</p> <p>13 MS. EATON: I did receive the</p> <p>14 pictures by e-mail on special request on</p> <p>15 Friday at the end of the day. I don't</p> <p>16 believe that those marketing materials</p> <p>17 were included in what I received.</p> <p>18 MR. BANKSTON: You may have not</p> <p>19 been forwarded everything from Ms. Lewis</p> <p>20 or whoever it was sent to, because</p> <p>21 those -- all I can tell you is that I</p> <p>22 personally made special efforts to</p> <p>23 collect those and make sure that they</p> <p>24 were sent in response to that request.</p> <p>25 MS. EATON: On Friday?</p>

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1 Y. DAVID

2 MR. BANKSTON: On Friday, correct.

3 MS. EATON: Of last week.

4 MR. BANKSTON: Correct. And those
 5 pictures, I'm also responsible for
 6 passing those along. Which is why I'm
 7 saying it's somewhat surprising, and I
 8 don't know why, if whoever our lead
 9 counsel is, in passing those e-mails
 10 along, if one didn't get sent or if one
 11 hit a spam box for one reason or
 12 another, but I can tell you that I am
 13 the one who collected those photos and
 14 made special efforts to get these
 15 materials here to you in response to the
 16 request for the marketing materials on
 17 the alternative design materials that
 18 are cited within his report.

19 So if you don't have those, I'm not
 20 totally prepared now to explain to you
 21 why you don't have them.

22 MS. EATON: That's fine. I just
 23 wanted to make a marker that I did not
 24 receive them. I don't believe I've
 25 received them, unless I made an error in

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1 Y. DAVID

2 my e-mails. I don't believe I've
 3 received them before today, and I have
 4 not had a chance to look through them
 5 all.

6 BY MS. EATON:

7 Q. So you can close that.
 8 (David Exhibit 8 marked.)

9 BY MS. EATON:

10 Q. I've marked as Exhibit 8 a table of
 11 contents for literature. Is that literature
 12 that you reviewed in connection with your work
 13 in this case?

14 A. Yes.

15 (David Exhibit 9 marked.)

16 BY MS. EATON:

17 Q. I've marked as Exhibit 9 a table of
 18 contents for certain documents that I could
 19 characterize broadly as company documents. Is
 20 it your belief that those would correspond to
 21 the listing of materials reviewed in your
 22 report?

23 A. They will correspond to footnotes,
 24 yes.

25 Q. Okay. There's an index that I have

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1 Y. DAVID

2 marked as Exhibit 9 that has certain
 3 descriptions of the documents. Did you make
 4 those descriptions or did someone else make
 5 those descriptions?

6 A. I believe that I have a clerical
 7 assistant for doing that.

8 Q. But who provided the substance of
 9 the descriptions?

10 A. I was given the information and the
 11 order where it should be.

12 Q. Did you dictate the substance of
 13 those descriptions on Exhibit 9? Is that what
 14 you're saying?

15 A. I'm saying what I said in -- on the
 16 telephone, with a clerk, yes.

17 Q. Are those all of the 3M or Arizant
 18 or Augustine Biomedical documents that you
 19 reviewed in connection with your work with
 20 this case? I should say I have also a 510(k)
 21 binder here, so in addition to that.

22 A. Okay. Yes.

23 Q. Were those documents provided to
 24 you in a single packet?

25 A. In a single packet? Provided in

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1 Y. DAVID

2 boxes, I guess.

3 Q. Were the documents listed on
 4 Exhibit 9 provided to you all at once,
 5 together?

6 A. I see. No, I don't think so.
 7 There are different boxes.

8 Q. Do you recall over what period of
 9 time those documents were provided?

10 A. I would say probably over a
 11 four-month period.

12 Q. In what years?

13 A. In the -- late 2016 to early 2017.

14 Q. Do you know how those documents
 15 were selected?

16 A. Well, they're mostly a response to
 17 material that I requested.

18 Q. What did you request that those
 19 would be responsive to?

20 A. I requested the information about
 21 the statement by company officers by
 22 plaintiff, management relating to product,
 23 product development, to changes to the
 24 product, to testing and any field reports that
 25 were received.

1 Y. DAVID

2 Q. What kind of field reports are you
3 interested in?

4 A. In the sales rep conveying
5 information of what they see happening in the
6 field.

7 Q. Is it your understanding that the
8 binder sitting in front of you contains all
9 documents that would respond to that series of
10 categories you just listed that have been
11 produced in this litigation?

12 A. I'm not sure that I'm following the
13 question.

14 Q. Do you believe that you received
15 all documents that have been produced in this
16 litigation that relate to the categories that
17 you just described?

18 A. I see. I do not know if it's all.

19 Q. Would you be surprised if all of
20 the design and testing documents for these
21 products are contained in that binder?

22 A. Are or are not?

23 Q. Are. Would you be surprised if
24 exhibit -- would it be surprising to you if
25 Exhibit 9 contains all of the testing and

1 Y. DAVID

2 design documents for the Bair Hugger devices?

3 A. No.

4 Q. You would expect that to be it?

5 A. I have no expectation. I wanted
6 the material and reviewed what they provided.

7 Q. Have you ever been involved in
8 designing a medical device?

9 A. No.

10 Q. Have you ever reviewed a design
11 history file?

12 A. No.

13 Q. Do you know what a design history
14 file is?

15 A. Yes.

16 Q. What is a design history file?

17 A. It's information collected from the
18 engineering aspect of making a product from
19 beginning to end.

20 Q. Are there any federal regulations
21 that govern the design of a medical device?

22 A. Federal regulation design, that
23 regulate the design? No. Federal regulation
24 is looking at general processes, guidelines.
25 There's no requirement, just expectation or

1 Y. DAVID

2 guidelines how to do things.

3 Q. Do any of the federal regulations
4 that you're aware of relate to how to design a
5 medical device?

6 A. No.

7 Q. Are you aware of any industry
8 standard that relates to how to design a
9 medical device?

10 A. There are many guidelines out there
11 by different groups and professional
12 association, consulting, that create a
13 recommended process, guidelines guiding
14 implementation of ideation or innovation, but
15 those are recommendations and guidelines.
16 There's no mandatory.

17 Q. Are you familiar with any
18 particular recommendation or guideline for
19 designing a medical device that is a prominent
20 one or often used by medical device
21 manufacturers?

22 A. Again, for designing, no, I'm not
23 aware. I'm aware of testing, but -- the
24 outcome, but not of design.

25 Q. And when you're speaking of

1 Y. DAVID

2 testing, are you thinking of, for example,
3 ASTM standards?

4 A. For example, or AAMI or ANSI.

5 Q. Would those be related to specific
6 tests and how you conduct specific tests?

7 A. Correct.

8 Q. Are you familiar with any industry
9 standard for risk assessment of a medical
10 device?

11 A. Not as a standard. Again, as a
12 guideline and as a recommendation and
13 acceptable practice, but not mandatory.

14 Q. And is there any particular
15 guideline or recommendation that you're
16 thinking of when you say that?

17 A. There are several I pointed out in
18 my report to an organization called MITRE,
19 M-I-T-R-E, and there are others that are
20 provided by the Food and Drug Administration
21 and furthermore by the ANSI organization,
22 A-N-S-I.

23 Q. The MITRE reference that you
24 provided in your report, is that something
25 that you have worked with before in your

<p>1 Y. DAVID</p> <p>2 professional capacity outside of litigation?</p> <p>3 A. I used it, yes.</p> <p>4 Q. It looked to me like that was</p> <p>5 related to the design of a system. Is that</p> <p>6 correct?</p> <p>7 A. That's correct.</p> <p>8 Q. I did not see any discussion in</p> <p>9 that reference about medical devices, and I</p> <p>10 just wanted to make sure I didn't miss</p> <p>11 anything. Is that fair?</p> <p>12 A. No, that's correct. The concept</p> <p>13 there is describing how to identify hazard and</p> <p>14 do a risk assessment of a system. They are a</p> <p>15 big conglomerate and then they look at system,</p> <p>16 and my interest in that was from hospital</p> <p>17 point of view, looking at disaster</p> <p>18 preparedness for medical technology.</p> <p>19 Q. Have you ever used that MITRE</p> <p>20 system in advising a hospital about disaster</p> <p>21 preparedness for medical technology?</p> <p>22 A. Correct.</p> <p>23 Q. What kind of disaster preparedness</p> <p>24 are you thinking of? What kind of failures</p> <p>25 might there be that that would relate to?</p>	<p>1 Y. DAVID</p> <p>2 A. The disaster planning for</p> <p>3 healthcare provider is a very important</p> <p>4 functionality because during any kind of</p> <p>5 disaster, man-made or natural, the population</p> <p>6 expected at hospitals will be up and running</p> <p>7 and able to care for the injured, and</p> <p>8 nevertheless, hospitals are dependent on</p> <p>9 systems and subjected to failure themselves.</p> <p>10 So this disaster preparedness</p> <p>11 system is completely targeted; the hospital</p> <p>12 and electrical grid, telecommunication, a</p> <p>13 monitoring system of patient, an oxygen line,</p> <p>14 ventilators. So not one of a kind, but system</p> <p>15 of equipment functioning. Air conditioning</p> <p>16 will be one of the systems.</p> <p>17 Q. And to the extent that medical</p> <p>18 devices -- let me ask that differently. Would</p> <p>19 medical devices even be contemplated within</p> <p>20 that assessment?</p> <p>21 A. Sure.</p> <p>22 Q. And to the extent that they would</p> <p>23 be contemplated, would it relate to how they</p> <p>24 could continue to function if, for example,</p> <p>25 the electrical grid goes down?</p>
<p>1 Y. DAVID</p> <p>2 A. That will be one example.</p> <p>3 Q. Is there another example that would</p> <p>4 relate to how medical devices would function</p> <p>5 in a disaster?</p> <p>6 A. Sure. If you do not have access to</p> <p>7 supply that the product is using, if an</p> <p>8 environment as far as air temperature, for</p> <p>9 example, cannot support the limit of the range</p> <p>10 of temperature that's designed for this device</p> <p>11 operation, if it goes outside the limitation,</p> <p>12 and if you have a situation where gas powering</p> <p>13 the device has been contaminated.</p> <p>14 Q. Have you ever applied ISO</p> <p>15 standard -- have you ever heard of the</p> <p>16 International Standards Organization and have</p> <p>17 any familiarity with its standards?</p> <p>18 A. Sure.</p> <p>19 Q. Have you ever used or applied ISO</p> <p>20 Standard 14971?</p> <p>21 A. I worked with it. I am not sure</p> <p>22 that I can tell you that I applied it in a</p> <p>23 project.</p> <p>24 Q. How did you work with it?</p> <p>25 A. Well, as part of my experience and</p>	<p>1 Y. DAVID</p> <p>2 training, I went to seminars. I educated</p> <p>3 myself as to what the standard's purpose and</p> <p>4 what the principle of the categories that it</p> <p>5 addresses, and how one will use it as contrast</p> <p>6 with other risk assessment programs.</p> <p>7 Q. What is ISO 14971? What is it</p> <p>8 intended -- what is it? What does it apply</p> <p>9 to?</p> <p>10 A. It's basically quality system</p> <p>11 organization.</p> <p>12 Q. I'm sorry. ISO Standard</p> <p>13 specifically 14971, do you know what that</p> <p>14 addresses?</p> <p>15 A. It's addressed risk management.</p> <p>16 Q. For what?</p> <p>17 A. For medical devices.</p> <p>18 Q. Did you consult that in connection</p> <p>19 with your work in this case?</p> <p>20 A. No, I don't believe so.</p> <p>21 Q. You are aware of it?</p> <p>22 A. I am.</p> <p>23 Q. You're aware that the risk in that</p> <p>24 standard is evaluated in connection with</p> <p>25 benefit?</p>

<p>1 Y. DAVID</p> <p>2 A. Risk usually has been evaluated and</p> <p>3 when you look at the system, the risk -- the</p> <p>4 benefit-to-risk ratio is a parameter that they</p> <p>5 take into consideration. But just to have</p> <p>6 risk assessment, you don't need to bring the</p> <p>7 benefits in.</p> <p>8 Q. In your work in hospitals, do</p> <p>9 you -- did your role ever involve considering</p> <p>10 both benefit and risk of certain medical</p> <p>11 technologies?</p> <p>12 A. Sometimes, yes.</p> <p>13 Q. If you were making a decision, for</p> <p>14 example, whether to purchase a particular</p> <p>15 device, would it be relevant to consider both</p> <p>16 the benefit and the risk of the device?</p> <p>17 A. Somewhere along the consideration</p> <p>18 that that parameter has an input.</p> <p>19 Q. When you were working at a hospital</p> <p>20 considering that type of framework, did you</p> <p>21 have any written standards or protocols that</p> <p>22 you were referencing?</p> <p>23 A. I don't think so.</p> <p>24 Q. Did you ever create any</p> <p>25 risk-benefit standard that would provide the</p>	<p>1 Y. DAVID</p> <p>2 criteria by which you would evaluate medical</p> <p>3 technology?</p> <p>4 A. I did not create standard. I</p> <p>5 created processes and protocol. So I did do</p> <p>6 those.</p> <p>7 Q. And in connection with -- were</p> <p>8 those ever reduced to writing?</p> <p>9 A. Those were reduced to writing,</p> <p>10 correct.</p> <p>11 Q. Was there anything in those</p> <p>12 protocols that would say this is how you</p> <p>13 should evaluate a benefit?</p> <p>14 A. I don't think so.</p> <p>15 Q. Within the context of federal</p> <p>16 regulation of medical devices, is risk</p> <p>17 evaluated in connection or in context with</p> <p>18 benefit?</p> <p>19 A. Sometimes.</p> <p>20 Q. Would you agree that the purpose of</p> <p>21 federal regulation of medical devices is to</p> <p>22 provide reasonable assurance of safety and</p> <p>23 effectiveness of those devices?</p> <p>24 A. I agree that that's the FDA</p> <p>25 mission.</p>
<p>1 Page 176</p> <p>2 Y. DAVID</p> <p>3 Q. Would you agree that under ISO</p> <p>4 14971, safety is defined as the absence of an</p> <p>5 unacceptable risk?</p> <p>6 A. As we sit here, I don't recall by</p> <p>7 heart the words, but that's close to what I</p> <p>8 would expect to find there.</p> <p>9 Q. And would you expect also that in</p> <p>10 the context of federal regulation, what we</p> <p>11 are -- what the government is seeking to avoid</p> <p>12 is an unreasonable risk in the context of how</p> <p>13 the product is used?</p> <p>14 A. That makes sense.</p> <p>15 Q. Are you familiar that that is in</p> <p>16 fact the standard, or no?</p> <p>17 A. Because there are classifications</p> <p>18 of risk, I would modify my response by saying</p> <p>19 that the risk -- the magnitude of risk.</p> <p>20 Q. Are you saying that that's in the</p> <p>21 regulation?</p> <p>22 A. Yes.</p> <p>23 Q. The magnitude of risk?</p> <p>24 A. Yes.</p> <p>25 Q. What regulation are you thinking</p>	<p>1 Page 177</p> <p>2 Y. DAVID</p> <p>3 A. The classification.</p> <p>4 Q. Class 1, 2 or 3?</p> <p>5 A. Correct.</p> <p>6 Q. Okay. And that when FDA is</p> <p>7 considering the risk, it is considering</p> <p>8 whether the magnitude of risk is unreasonable</p> <p>9 in light of the overall risk-benefit context.</p> <p>10 Would you agree with that?</p> <p>11 A. I would agree.</p> <p>12 (David Exhibit 10 marked.)</p> <p>13 BY MS. EATON:</p> <p>14 Q. Exhibit 10 is a table of contents</p> <p>15 to a 510(k) for the model 505 and the model</p> <p>16 750. Is that correct?</p> <p>17 A. Yes.</p> <p>18 Q. Did you review those documents?</p> <p>19 A. Yes.</p> <p>20 (David Exhibit 11 marked.)</p> <p>21 BY MS. EATON:</p> <p>22 Q. And Exhibit 11 is a table of</p> <p>23 contents for depositions of certain</p> <p>24 individuals. Is that correct?</p> <p>25 (Document review by witness.)</p> <p>--oOo--</p>

1 Y. DAVID
 2 BY MS. EATON:
 3 Q. First, just is it correct that
 4 Exhibit 11 is a table of contents listing
 5 certain depositions?
 6 A. Yes.
 7 Q. And then were you wanting -- I'm
 8 estimating that perhaps you were wanting to
 9 compare that list to the list contained in
 10 your report?
 11 A. Correct.
 12 Q. Okay. So Exhibit 3 --
 13 A. I need my glasses.
 14 Q. It lists nine depositions on
 15 Exhibit 3. Are there nine there?
 16 A. There are nine, yes.
 17 Q. Okay. I don't see a deposition of
 18 Mr. Ulatowski in Exhibit 11 and I didn't see
 19 it in the box. Do you believe you have in
 20 some form reviewed the deposition of
 21 Mr. Ulatowski?
 22 A. I believe it's inserted here.
 23 Q. I don't need you to look for it
 24 right now, that's okay. You do believe you've
 25 reviewed that deposition, correct?

1 Y. DAVID
 2 deposition but you believe you had the whole
 3 transcript?
 4 A. Right.
 5 Q. Okay. Any other transcript you
 6 believe you had?
 7 A. No.
 8 Q. Any other expert report you believe
 9 you had that's -- other than the three listed
 10 in Exhibit 3?
 11 A. No.
 12 Q. How did you obtain this document,
 13 "Medical Devices and the Public's Health,"
 14 about the 510(k) clearance process?
 15 A. I've asked counsel to produce a
 16 hard copy.
 17 Q. How did you know of this document?
 18 A. Part of my practice is to stay on
 19 top of what's happening with the regulatory
 20 field and it's one of the things that I would
 21 be reading.
 22 Q. Okay. I think you said something
 23 about an FDA -- this document -- okay, let
 24 me -- I'm sorry, let me take that and ask
 25 differently.

1 Y. DAVID
 2 A. Yes.
 3 Q. And do you believe you have
 4 reviewed any other deposition besides
 5 Mr. Ulatowski's that we would not find in
 6 Exhibit 11 or in Exhibit 3?
 7 A. No. But I believe that I inserted
 8 it.
 9 Q. Into one of the tabs?
 10 A. Yes.
 11 Q. Okay. I didn't see any table of
 12 contents for any expert reports. Do you
 13 believe that you brought with you today the
 14 expert reports that you reviewed?
 15 Just to show you, your box is now
 16 empty. And also, to be complete, there is a
 17 document I pulled from the box. Just it
 18 wasn't in a notebook. It's titled "Medical
 19 Devices and the Public's Health: The FDA
 20 510(k) Clearance Process At 35 Years."
 21 A. There's only one page of Ulatowski
 22 deposition here. I thought that I put it in.
 23 I don't know what happened.
 24 Q. So now looking in your notebook,
 25 you're seeing one page of the Ulatowski

1 Y. DAVID
 2 Was there any document that was an
 3 FDA guidance that you used to inform your
 4 opinions about the regulatory history of the
 5 Bair Hugger devices?
 6 A. Can you ask me again the question?
 7 Q. Was there any specific FDA guidance
 8 document that informed your evaluation of the
 9 regulatory history of the Bair Hugger devices?
 10 MR. BANKSTON: Object to the form.
 11 A. I think the overall environment of
 12 FDA regulation documents like the 510(k)
 13 submission process.
 14 BY MS. EATON:
 15 Q. Have you ever worked within the
 16 Office of Device Evaluation for FDA?
 17 A. Worked for the FDA? No. I just
 18 serve as a consultant for them.
 19 Q. I do want to get to that in a
 20 moment, so let me just ask some specific
 21 questions. You've never been an employee of
 22 the FDA. Is that correct?
 23 A. That is correct.
 24 Q. You have never worked within the
 25 Office of Device Evaluation?

1 Y. DAVID
 2 A. That is correct.
 3 Q. Have you ever worked within the
 4 Office of Compliance?
 5 A. I did not.
 6 Q. Have you ever taken part in
 7 reviewing a 510(k) application for clearance?
 8 A. Yes.
 9 Q. On behalf of the FDA?
 10 A. Yes.
 11 Q. In what context?
 12 A. As a member of the advisory panel.
 13 Q. Okay. When did you do that work?
 14 A. It's a public record when the panel
 15 is called to admitting. You can find them
 16 online. I don't recall when it was done.
 17 Q. Was it once or more than once?
 18 A. More than once.
 19 Q. How many devices -- you're saying
 20 as part of your work on the panel, you've
 21 reviewed a 510(k) application?
 22 A. Yes.
 23 Q. Okay. For how many devices?
 24 A. I don't know, four, five.
 25 Q. Do you recall what the devices are?

1 Y. DAVID
 2 questions the panel was being asked at the
 3 times that you met?
 4 A. The specific question? No, I don't
 5 remember.
 6 Q. Do you remember the scope of the
 7 review you were asked to make?
 8 A. The scope of the review was to
 9 determine if the instructions for use are
 10 sufficiently covering the risk associated with
 11 the use.
 12 Q. In all of the cases that you
 13 recall, that was your scope?
 14 A. In all the cases?
 15 Q. I'm sorry. I believe I heard you
 16 say you thought -- I should -- I should say
 17 that differently.
 18 You said you recalled that you
 19 reviewed perhaps four or five devices. Did
 20 that occur in one panel meeting or over
 21 several panel meetings?
 22 A. Over several.
 23 Q. In each situation where you were
 24 asked to review something for this panel that
 25 you've identified, was the scope of the review

1 Y. DAVID
 2 A. No.
 3 Q. And I want to be clear. Let's take
 4 a look at your CV, which is within Exhibit 3.
 5 If you would please turn to your CV and find
 6 for me which specific panel you're referring
 7 to.
 8 A. On page 3 it's the General Hospital
 9 and Personal Use Devices Panel.
 10 Q. Okay. The time frame here listed
 11 is 1993 to present for that. Is that correct,
 12 that you are still on that panel?
 13 A. Yes.
 14 Q. And have you been on that panel
 15 since 1993 continuously?
 16 A. Since 1993, correct.
 17 Q. Is that type of work something that
 18 is -- is there any kind of regular meeting of
 19 that panel?
 20 A. No.
 21 Q. How many times was the panel called
 22 that you participated in?
 23 A. I don't recall. But like I said,
 24 it's a public record.
 25 Q. Do you remember the specific

1 Y. DAVID
 2 to determine if IFUs sufficiently covered the
 3 risks?
 4 A. No. There were additional charges
 5 for the panel. A second one was to determine
 6 if the submitter identified sufficient risk
 7 that might be existing in the clinical
 8 environment when the device is in use.
 9 Q. Any other scope of review you could
 10 recall?
 11 A. Is there sufficient -- if there is
 12 sufficient content in the classification of
 13 the device to ensure safety when this device
 14 is deployed, or there is a need for special
 15 control to be added.
 16 Q. Do you recall what device that was?
 17 A. That was some kind of injector.
 18 Q. Injector?
 19 A. Yes.
 20 Q. Do you recall what kind of devices
 21 you reviewed IFUs for?
 22 A. No.
 23 Q. Any other scope of review you can
 24 recall?
 25 A. There is another panel on the same

<p>1 Y. DAVID</p> <p>2 page 3 that I identify as a consultant for FDA</p> <p>3 on neurological devices.</p> <p>4 Q. Yes.</p> <p>5 A. And in that meeting, there was a</p> <p>6 question about 510(k) that was submitted for a</p> <p>7 drug that is using a device to deliver it.</p> <p>8 Q. Do you recall the specific</p> <p>9 combination device?</p> <p>10 A. Not beyond that.</p> <p>11 Q. I'm sorry?</p> <p>12 A. Not beyond that.</p> <p>13 Q. Okay. With respect to your work on</p> <p>14 the neurological devices panel or for</p> <p>15 neurological devices, this entry in your CV,</p> <p>16 was that one product review the extent of your</p> <p>17 work for this category?</p> <p>18 A. I believe so.</p> <p>19 Q. When is the last time that you were</p> <p>20 called to consult as part of the panel in the</p> <p>21 Center for Devices and Radiologic Health?</p> <p>22 A. Oh, that was quite some time ago.</p> <p>23 Maybe 2006.</p> <p>24 Q. I'm not sure how far back the FDA</p> <p>25 records go online and how easy it would be for</p>	<p>1 Y. DAVID</p> <p>2 me to find any of the records that you're</p> <p>3 referring to. Is it your belief that you</p> <p>4 participated every time the General Hospital</p> <p>5 and Personal Use Devices Panel has been called</p> <p>6 since 1993?</p> <p>7 A. No. There are times that I was</p> <p>8 involved with projects overseas and hospitals</p> <p>9 in China, Israel, Italy, and I wasn't</p> <p>10 available for a meeting. There are times that</p> <p>11 due to work at the Medical Center I could not</p> <p>12 attend, so, no, I did not attend all the</p> <p>13 meetings.</p> <p>14 Q. Do you have any materials from</p> <p>15 which you would look and let me know which</p> <p>16 times you did participate and in what years</p> <p>17 and for what products?</p> <p>18 A. No. This material got lost in a</p> <p>19 flood that the Medical Center suffered, so I</p> <p>20 don't have that.</p> <p>21 Q. Is there a particular expertise you</p> <p>22 have that you're aware results in you being</p> <p>23 chosen or asked to serve on certain panels?</p> <p>24 A. Sure.</p> <p>25 Q. What is that expertise?</p>
<p>1 Y. DAVID</p> <p>2 A. Biomedical engineering, trained and</p> <p>3 practice in the largest medical center in the</p> <p>4 country so I am bringing the engineering and</p> <p>5 the clinical exposure and appreciation for</p> <p>6 processes involve technology in patient care</p> <p>7 environment. It's a unique combination.</p> <p>8 Q. Have you ever been involved in</p> <p>9 reviewing a question of whether a device was</p> <p>10 substantially equivalent to a predicate</p> <p>11 device?</p> <p>12 A. During the panel convening that the</p> <p>13 question would come up, yes.</p> <p>14 Q. You have a specific recollection</p> <p>15 that you've been asked to review that</p> <p>16 question?</p> <p>17 A. I have specific recollection that</p> <p>18 that was one of the subjects that we're asked</p> <p>19 to consult upon. I don't have a specific</p> <p>20 recollection what device was involved.</p> <p>21 Q. Do you have a specific recollection</p> <p>22 of what types of information were consulted or</p> <p>23 considered in that, in connection with that</p> <p>24 question?</p> <p>25 A. From my angle, what I remember are</p>	<p>1 Y. DAVID</p> <p>2 questions relating to biomedical engineering</p> <p>3 in the clinical environment. So if I'm not</p> <p>4 mistaken, one of the devices was a cleaning</p> <p>5 and sterilizing equipment for proctoscopes,</p> <p>6 scopes that are used in the rectum, and how</p> <p>7 you clean it between uses. And this cleaner</p> <p>8 has a predicate device that said here is why</p> <p>9 we are substantially equivalent.</p> <p>10 The question was relating to how in</p> <p>11 the real world, in a clinical environment,</p> <p>12 this other device is being used.</p> <p>13 Q. Any other instance you can recall</p> <p>14 being asked to evaluate a substantial</p> <p>15 equivalence question?</p> <p>16 A. No.</p> <p>17 Q. Have you ever inspected a</p> <p>18 manufacturer on behalf of FDA?</p> <p>19 A. No.</p> <p>20 Q. Have you ever had any input into</p> <p>21 any FDA compliance decision?</p> <p>22 A. No.</p> <p>23 Q. Have you ever been consulted in any</p> <p>24 of these panels with respect to whether a</p> <p>25 device was adulterated or misbranded?</p>

<p>1 Y. DAVID</p> <p>2 A. No.</p> <p>3 Q. What is the definition of an</p> <p>4 adulterated device?</p> <p>5 A. A device that has been put on the</p> <p>6 market with -- featuring performances other</p> <p>7 than were reported.</p> <p>8 Q. Reported to whom?</p> <p>9 A. To the regulatory agency.</p> <p>10 Q. How does something become a</p> <p>11 specification or standard against which the</p> <p>12 regulatory agency would have the ability to</p> <p>13 compare to determine if a device is</p> <p>14 adulterated?</p> <p>15 A. By comparing the information</p> <p>16 submitted in the -- if you will take it as a</p> <p>17 class 2 device, in the 510(k) documents with</p> <p>18 the actual device performing in the field.</p> <p>19 Q. The device would need to be</p> <p>20 manufactured to the specification stated to</p> <p>21 the FDA. Is that correct?</p> <p>22 A. Would have to, yes.</p> <p>23 Q. What is the definition of</p> <p>24 misbranding?</p> <p>25 A. Misbranding is providing</p>	<p>1 Y. DAVID</p> <p>2 information that is lacking sufficient</p> <p>3 assurance of safe application.</p> <p>4 Q. From where do you get that</p> <p>5 definition?</p> <p>6 A. Where I get the information, I will</p> <p>7 go to the Code of Federal Regulation.</p> <p>8 Q. And do you know where in the Code</p> <p>9 of Federal Regulation I will find that</p> <p>10 definition?</p> <p>11 A. I think my report is identifying a</p> <p>12 specific area. There is too much material</p> <p>13 here for me to remember by heart.</p> <p>14 Q. Have you ever been involved on</p> <p>15 behalf of a company responding to any</p> <p>16 statement by FDA that a device was adulterated</p> <p>17 or misbranded in FDA's view?</p> <p>18 A. I have not been involved in a</p> <p>19 company such as that.</p> <p>20 Q. Have you ever in your professional</p> <p>21 capacity in any way, outside of litigation,</p> <p>22 applied, interpreted or addressed the words</p> <p>23 "adulterated" or "misbranded"?</p> <p>24 A. Sure.</p> <p>25 Q. Tell me about that.</p>
<p>1 Page 192</p> <p>2 Y. DAVID</p> <p>3 A. Throughout my practice at the</p> <p>4 Medical Center, I was evaluating medical</p> <p>5 technologies as we discussed this morning and</p> <p>6 I would look to see that information provided</p> <p>7 to me by the manufacturers is the same that</p> <p>8 the device is presenting and that the claims</p> <p>9 that are being made for the device performance</p> <p>10 are the same that I'm measuring.</p> <p>11 Q. Okay. In terms of the terms</p> <p>12 "adulterated" and "misbranded," I meant the</p> <p>13 application of the statute. Would you be</p> <p>14 applying a federal statute or regulation in</p> <p>15 the course of your work?</p> <p>16 A. No. I'm not involved in the legal</p> <p>17 profession.</p> <p>18 Q. And do you have any understanding</p> <p>19 about whether -- let's see. Do you have any</p> <p>20 understanding that FDA ever communicates to</p> <p>21 companies a statement that a device is either</p> <p>22 adulterated or misbranded?</p> <p>23 A. The FDA would.</p> <p>24 Q. In what context would the FDA do</p> <p>25 that?</p> <p>26 A. If they identify that to be the</p>	<p>1 Page 193</p> <p>2 Y. DAVID</p> <p>3 case. It can be product investigation, a</p> <p>4 facility inspection, field complaints.</p> <p>5 Q. Have you ever heard of a document</p> <p>6 called a warning letter?</p> <p>7 A. Yes.</p> <p>8 Q. Have you ever reviewed a warning</p> <p>9 letter in your professional capacity outside</p> <p>10 of litigation?</p> <p>11 A. You're asking me questions that I</p> <p>12 need to scan 40 years of practice, and my</p> <p>13 response to you would be simply yes because</p> <p>14 I've worked with thousands and thousands of</p> <p>15 manufacturers. And as I told you this</p> <p>16 morning, I was responsible for over 25,000</p> <p>17 medical devices and every now and then there</p> <p>18 will be a warning letter issued. There will</p> <p>19 be other ways to recall or field modification,</p> <p>20 and I'm familiar with the process, familiar</p> <p>21 with the communication and have worked with</p> <p>22 them.</p> <p>23 Q. Okay. In the course of your work</p> <p>24 in the hospital, are you saying as the</p> <p>25 director of the biomedical engineering</p> <p>26 department you might encounter a warning</p>

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1 Y. DAVID

2 letter for a product? Is that what you mean
 3 to say? Or have I interpreted you correctly?

4 A. Yes.

5 Q. Would you go looking for that type
 6 of communication from FDA or would you
 7 sometimes receive it?

8 A. No. I would look for it.

9 Q. Okay. Why would you look for it?

10 A. Because I might receive information
 11 from a clinician that they cannot access a
 12 device or accessory anymore and I would look
 13 to see if that's one of the reasons.

14 Q. Did you make any search in this
 15 case to see if there were any warning letters
 16 issued by FDA to 3M or Arizant or Augustine?

17 A. The work I've done are in these
 18 binders, so if you don't see it here, I did
 19 not do it.

20 Q. When you were working for a
 21 hospital, how would you go look for a warning
 22 letter? What method would you use?

23 A. Oh, there's a couple of ways. One
 24 is communicate with the manufacturer directly
 25 and raise the issue and ask the question.

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1 Y. DAVID

2 me and literature that I read, I did not see
 3 that.

4 Q. Did you review any databases to see
 5 if there had been a recall or a field notice?

6 A. I think we discussed that I did not
 7 look for warning letters.

8 Q. But I'm asking a different
 9 question. Did you look for recall notices?

10 A. Did I look for recall notices? No,
 11 I don't think so.

12 Q. Do you know if FDA has inspected 3M
 13 with respect to the Bair Hugger device since
 14 2010? Since it acquired the product, I should
 15 say.

16 A. I'm aware of one EIR. I don't
 17 remember the year that it was done.

18 Q. I believe you do reference an EIR
 19 in your report. Is that the one you're
 20 thinking of?

21 A. Yes.

22 Q. Do you know if since the date of
 23 that EIR there has been any other inspection
 24 by FDA of 3M with respect to the Bair Hugger
 25 device?

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1 Y. DAVID

2 Secondary is to visit with the FDA publicly
 3 accessible database.

4 Q. And did you visit with the FDA
 5 publicly accessible database in this case at
 6 all?

7 A. On the issue of warning letters,
 8 no.

9 Q. Would it be important to you to
 10 know if the FDA has issued a warning letter or
 11 not to 3M with respect to the Bair Hugger
 12 device?

13 A. I think it will be important if I
 14 would have a base to think that there is a
 15 base for suggesting someone exist. But like I
 16 said before, since there was no recall of the
 17 product from the field, since there was no
 18 field corrections or "Dear Doctor" letters
 19 issued by the manufacturers, I did not imagine
 20 that one exists.

21 Q. What is the basis for your
 22 statement that there were no "Dear Doctor"
 23 letters or recalls for the product?

24 A. Because as I'm reviewing the
 25 various databases and information provided to

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1 Y. DAVID

2 A. No.

3 Q. Would that matter to you?

4 A. If there was another inspection
 5 relating to the Bair Hugger at the
 6 manufacturing site, that would be important.

7 Q. Would it matter to you if FDA had
 8 considered specifically whether or not -- let
 9 me ask you a different question.

10 Why?

11 A. Why? Because usually you can see
 12 what is the reason that the inspection took
 13 place or initiated it for cause or a routine
 14 periodic site inspection. Secondary, you can
 15 see what was the target of the visits, what
 16 are the issues that were raised during the
 17 visit or the observation, as I call it. And
 18 finally, what was the resolution.

19 Q. And if FDA specifically considered
 20 the question of whether Bair Hugger devices
 21 increased infection risk, for example, and
 22 concluded that they made no observations or
 23 findings at the end of that inspection, would
 24 that be important to you?

25 A. It will be important to read, yes.

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1 Y. DAVID

2 Q. In your professional capacity
 3 outside of litigation, have you ever had
 4 reason to review an inspection report from the
 5 agency?

6 A. Outside litigation, no.

7 Q. And have you ever consulted with
 8 FDA in the preparation of an Establishment
 9 Inspection Report?

10 A. No.

11 Q. You said that you have consulted
 12 with -- I'm sorry, let me just ask a better
 13 question.

14 Have you ever consulted with
 15 medical device companies about regulatory
 16 topics?

17 A. Yes.

18 Q. Are you able to identify any of the
 19 companies for me?

20 A. On page 2 of my CV under
 21 "Professional Experience," you have "Interim
 22 CEO, Canopy Edge." That's specifically
 23 involved with preparing the product for
 24 regulatory submission.

25 Q. What is that product?

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1 Y. DAVID

2 A. It is a vascular catheter.

3 Q. Has a 510(k) -- I'm sorry. Will
 4 that be submitted as a 510(k) or a PMA, do you
 5 know?

6 A. It is still being reviewed.

7 Q. Any other medical device for which
 8 you've provided consulting on regulatory
 9 topics?

10 A. There are two other companies. One
 11 is called, I believe, Carmel Industries,
 12 C-A-R-M-E-L. And the other one is Begamed,
 13 B-E-G-A-M-E-D.

14 Q. What products?

15 A. Begamed.

16 Q. Were there specific products?

17 A. Begamed's product is laparoscopic
 18 suture, surgical instrument. And Carmel
 19 Industry is a software-based labor and
 20 delivery package.

21 Q. With respect to these three
 22 products that you've just identified, what is
 23 your role? What type of regulatory advice are
 24 you providing?

25 A. Wait a second. There is one more.

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1 Y. DAVID

2 There is one more and I can't remember the
 3 name. But their product, this additional
 4 entity, their product is a brain stimulator.
 5 And let me answer your question about what
 6 they asked me to do. The brain stimulator was
 7 going to submit a 510(k) and wanted to know
 8 what are the electrical safety terms and
 9 conditions that their testing needed to
 10 demonstrate compliance with.

11 Q. Okay.

12 A. IEC 60601-1.

13 The Carmel Industry, they wanted to
 14 know if there is a predicate device to their
 15 product that they can use for substantial
 16 equivalency.

17 The Begamed wanted to understand if
 18 their product will be qualified for 510(k) if
 19 there are substantial equivalent predicate
 20 devices and if there is a requirement for
 21 animal testing.

22 Q. Are sutures what class?

23 A. Class 2.

24 Q. What about the software-based labor
 25 and delivery package?

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1 Y. DAVID

2 A. I don't remember.

3 Q. Do you remember for the brain
 4 stimulator?

5 A. Class 2.

6 Q. And the vascular catheter is still
 7 under evaluation?

8 A. Correct.

9 Q. For the vascular catheter, what is
 10 the advice you're being asked about to
 11 provide?

12 A. What type of testing and
 13 information will be required for submission.

14 Whenever we can take a break...

15 Q. Pardon? Sure.

16 THE VIDEOGRAPHER: We are going off
 17 the record at 15:20.

18 (Recess, 3:20 p.m. to 3:32 p.m.)

19 THE VIDEOGRAPHER: We are back on
 20 the record at 15:32.

21 BY MS. EATON:

22 Q. Dr. David, have you ever designed a
 23 patient warming device?

24 A. No.

25 Q. Have you ever made or published any

1 Y. DAVID
 2 presentation on Bair Hugger devices?
 3 A. No.
 4 Q. Before your work in this case, had
 5 you ever read any studies related to Bair
 6 Hugger devices?
 7 A. No.
 8 Q. At any time, have you performed
 9 testing related to Bair Hugger devices other
 10 than what we have discussed today?
 11 A. No.
 12 Q. At any time, have you performed
 13 research related to Bair Hugger devices that
 14 is not either reflected in your report or in
 15 what we have discussed today?
 16 A. No.
 17 Q. Have you undertaken any effort --
 18 sorry, let me ask that differently.
 19 Before your work in this case, had
 20 you reviewed any hospital practices with
 21 respect to Bair Hugger devices?
 22 A. A specific brand name Bair Hugger,
 23 no. But relating to patient warming, yes.
 24 Q. What had you reviewed related to
 25 patient warming prior to your work in this

1 Y. DAVID
 2 case?
 3 A. Patient warming is a very important
 4 part of maintaining patient condition during
 5 disease management and following surgery or
 6 during trauma, so as part of my responsibility
 7 as director of biomedical engineering, for
 8 over 30 years I was involved in reviewing
 9 warming devices for adult and pediatric
 10 patients using either a literally oven-warmed
 11 blanket or devices that use fluids to warm
 12 patients or cool them or radiation-based
 13 devices that they are used in different
 14 environments.
 15 The specific sensitivity that I
 16 became very familiar with the warming
 17 technology of patients is the one involving
 18 pediatrics, and we were having a very
 19 interesting project where we were trying to
 20 put warming devices in the emergency room, in
 21 the trauma center where the ambulances would
 22 bring babies, and determine how fast we can
 23 bring their body temperature up in those
 24 trauma situations.
 25 And we were putting an infrared

1 Y. DAVID
 2 warming device in the ceiling of the trauma
 3 center and making testing and examination of
 4 mannequin, small size, having ice cube on
 5 them, and determine the temperature change of
 6 the body. And this specific example that I
 7 became intimately familiar with the issue of
 8 maintaining or warming patients under trauma
 9 situations.
 10 The other example that I would like
 11 to bring in front of you is the neonatology
 12 arena where premature babies are born and are
 13 not able to maintain their body temperature,
 14 not because of trauma or disease, just because
 15 of their stage in early life. And those
 16 babies are tremendously sensitive to body core
 17 temperatures and it's very difficult to warm
 18 them up without causing skin damage.
 19 So infant warmers, Isolettes, those
 20 are warm air, forced warm air contraption
 21 boxes that you put babies in and need to have
 22 specific monitoring for the humidity and the
 23 temperature inside to make sure that the
 24 babies are not drying up and not being
 25 basically cooked.

1 Y. DAVID
 2 And we did many studies and
 3 published several research papers on that, and
 4 I developed a protocol to -- how to test those
 5 devices later on in their life. So once we
 6 developed it, we learned how to use it and how
 7 to maintain and service it.
 8 Q. Did you mean later on in the life
 9 of the device or --
 10 A. Correct, yes. Thank you.
 11 Q. That's what I thought in context as
 12 opposed to the life of the babies.
 13 Did you do -- you meant the device?
 14 A. Yes.
 15 Q. Okay. Did any aspect of your
 16 testing or evaluation with respect to the
 17 Isolettes used for premature babies relate to
 18 contamination or infection risk?
 19 A. It has that aspect and we have
 20 epidemiologists that were part of the study
 21 and that was their responsibility to collect
 22 the data and look at the statistics. So it
 23 was not something that I would do.
 24 Q. Okay. Are you familiar with any of
 25 their determinations or the results of their

1 Y. DAVID

2 determinations about what factors might affect
 3 contamination or infection risk? Let me say
 4 that differently.

5 Do you know what they were even
 6 looking at?

7 A. Yes, I know what they were looking
 8 at and how they were measuring it, but that
 9 was not my part or responsibility in that line
 10 of work.

11 Q. What were they measuring?

12 A. They're basically looking at
 13 cultures and swabs and looking at spores and
 14 bacteria growth and colony-forming units,
 15 CFUs, and changes in those specific area of
 16 where the air is going.

17 Q. Were those taken from inside of the
 18 baby-warming box?

19 A. Correct.

20 Q. That was not work you were involved
 21 with?

22 A. Correct.

23 Q. Did you mean to say they were
 24 epidemiologists doing that?

25 A. Yes.

1 Y. DAVID

2 Q. Do you have any expertise in
 3 determining how one would test for bacteria in
 4 an environment?

5 A. I would refer to the expert on
 6 that. I have working knowledge, as we just
 7 described, being in the environment, seeing
 8 what they're collecting. But I wouldn't
 9 present myself as expert in that field.

10 Q. Okay. With respect to the first
 11 situation you mentioned, pediatric trauma, was
 12 that heat -- I'm sorry, let me say that
 13 differently.

14 Were those patients enclosed in any
 15 way to help with warming, or were they simply
 16 placed in a room?

17 A. You're right. What one needs to
 18 think about that during trauma, there is a
 19 large number of clinicians involved with
 20 things. There might be an anesthesiologist
 21 and a surgeon and a nurse. Everybody has
 22 something to do with the patient, so the
 23 patient cannot be contained. The patient is
 24 definitely open. It is environment similar to
 25 operating room in that there is a central

1 Y. DAVID

2 surgical table. Hopefully you don't have to
 3 do surgery there, but that's how you get
 4 access, 360 degrees around the patient, by the
 5 different people, and that's what was the
 6 study involved with.

7 Q. Was that a published study?

8 A. I think that the trauma surgeon --
 9 the trauma physician, he is not -- she is not
 10 a surgeon -- continues it. I'm not sure if it
 11 was published or where was it published. But
 12 she was definitely making presentation about
 13 it at different meetings.

14 Q. Was there a particular warming
 15 technology that you ultimately decided upon in
 16 that situation?

17 A. We tried different things and we
 18 settled on the radiation panel that came from
 19 the ceiling and were dropped on the patient
 20 once the patient was in place.

21 The drawback was that the heating
 22 element, the radiated heating element, is
 23 heating, nondiscriminately, anybody in the
 24 environment, not just the patient. So
 25 individuals that were tall and closer to the

1 Y. DAVID

2 radiating panel were absorbing more heat than
 3 the patient him or herself. That was a
 4 drawback.

5 Q. Was a consideration of
 6 contamination or infection risk any part of
 7 the evaluation in that trauma setting?

8 A. Not in that study, no.

9 Q. Any other time in your work outside
 10 of litigation that you have been personally
 11 involved in evaluating patient warming?

12 A. Yes. The other example would be in
 13 the cardiovascular theater, cardiovascular
 14 operating room. I don't know, Counsel, if
 15 you're aware, but the St. Luke's Episcopal
 16 Hospital that I was involved with is the home
 17 of the Texas Heart Institute, which is the
 18 highest-volume heart surgery hospital --
 19 institution in the country, maybe in the
 20 world.

21 So they are having significant
 22 amount of large volume of heart surgery with
 23 patients that are being cooled down on
 24 purposely to slow the metabolism and
 25 blood-brain barrier.

<p>1 Y. DAVID</p> <p>2 Those patients are expected to be</p> <p>3 well monitored and controlled as far as where</p> <p>4 their core temperature is, and when they are</p> <p>5 being brought back, there should be a certain</p> <p>6 rate of core temperature rising that one</p> <p>7 should expect to see, no faster, no slower.</p> <p>8 You do that with what the CDC meeting was here</p> <p>9 about, fluid warming and cooling devices. And</p> <p>10 you circulate the blood through a cooler</p> <p>11 element or a heating element, and these</p> <p>12 heating or cooling elements are devices that I</p> <p>13 was responsible for and participated in the</p> <p>14 study.</p> <p>15 We published a couple of studies on</p> <p>16 those -- I don't think that they are on my</p> <p>17 CV -- at the Texas Heart Institute Journal</p> <p>18 about the temperature control devices for</p> <p>19 postcardiac surgery, and I think there is one</p> <p>20 study that is in my list that is looking at</p> <p>21 outcome of patient that underwent cardiac</p> <p>22 surgery and their scalp temperature did not</p> <p>23 rise fast enough to predict their outcome.</p> <p>24 Q. Did any of the studies that you</p> <p>25 took part in or the publications have anything</p>	<p>1 Y. DAVID</p> <p>2 to do with infection risk?</p> <p>3 A. Of course when you're talking about</p> <p>4 the fluid-based warm or cooling device like in</p> <p>5 the cardiovascular area, when you put ice in a</p> <p>6 container and circulate blood around it or</p> <p>7 when you put heating element and circulate</p> <p>8 blood around it, of course there is the issue</p> <p>9 of infection and containment of bioburden</p> <p>10 pathogens. But once again, I was lucky to be</p> <p>11 in an institution that have their own</p> <p>12 expertise in that field, and that was not</p> <p>13 something that I was doing.</p> <p>14 Q. Do you know what kind of</p> <p>15 heater/cooler device was used in St. Luke's</p> <p>16 Hospital at any time?</p> <p>17 A. Yes, I know. I was going to say</p> <p>18 COBE, C-O-B-E, maybe Cincinnati Sub-Zero.</p> <p>19 There's another big manufacturer of heart-lung</p> <p>20 bypass machines that use those devices. I</p> <p>21 don't recall the brand.</p> <p>22 Q. Do you still consult with the</p> <p>23 biomedical or work for the biomedical</p> <p>24 engineering department of any hospital right</p> <p>25 now?</p>
<p>1 Y. DAVID</p> <p>2 A. I still have on-demand consultation</p> <p>3 with the hospital in Silicon Valley, and I</p> <p>4 finished consulting with the Adventist</p> <p>5 Healthcare System in California, who is a</p> <p>6 biomedical program. So right now, as of</p> <p>7 today, just on-demand.</p> <p>8 Q. The reference you made, I think, to</p> <p>9 the heater/cooler devices related to the</p> <p>10 HICPAC -- H-I-C-P-A-C -- document you cited.</p> <p>11 Is that right?</p> <p>12 A. Right.</p> <p>13 Q. Have you been involved with any</p> <p>14 hospital in assessing its practices in light</p> <p>15 of the issue that is described there?</p> <p>16 A. I don't think so.</p> <p>17 Q. Have you been involved in</p> <p>18 consulting with any hospital with respect to</p> <p>19 the use of heater/cooler devices and whether</p> <p>20 or not the use of those poses any infection</p> <p>21 risk?</p> <p>22 A. Well, naturally, for three decades</p> <p>23 or so I did that here at the Texas Medical</p> <p>24 Center and I described those occasions. Prior</p> <p>25 to that, I was at West Virginia University</p>	<p>1 Y. DAVID</p> <p>2 Medical Center and, again, the cardiovascular</p> <p>3 program was at the time developed and I worked</p> <p>4 with Dr. Tarnay, who was a cardiovascular</p> <p>5 surgeon, about cooling and warming patients</p> <p>6 with particular devices at the time.</p> <p>7 But I don't believe that my</p> <p>8 involvement was in the area of infections or</p> <p>9 infection prevention.</p> <p>10 Q. Do you recall any discussion, in</p> <p>11 any of your work outside of litigation, where</p> <p>12 a hospital was considering removing devices</p> <p>13 from the operating room because of air blowing</p> <p>14 from the devices?</p> <p>15 A. Not exactly what you are asking,</p> <p>16 but I was involved in reviewing and evaluating</p> <p>17 operating room pollutions from</p> <p>18 anesthesia-based gases that are expelled from</p> <p>19 a patient after they breathe it. And the</p> <p>20 records are suggesting that a minute amount of</p> <p>21 those gases, if exposed by operating room</p> <p>22 staff, that person, people, would lead to</p> <p>23 miscarriages and other undesirable outcome.</p> <p>24 So I was involved in study to</p> <p>25 monitor the influence of air exchanges in the</p>

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2 surgical theater and the amount of gas coming
 3 from the end of the anesthesia machine when
 4 mannequins were connected with simulated lungs
 5 to them. That probably is as close as I can
 6 come to your question.

7 Q. Have you ever been involved in
 8 designing a cleaning protocol for an operating
 9 room or for the equipment in it?

10 A. There is equipment that is being
 11 circulated through the operating room, not
 12 necessarily you would call it operating room
 13 fixed equipment, but the specific example I
 14 have in mind for you is infusion pump, and
 15 drug administration medical devices such as
 16 infusion pump are probably in the thousands in
 17 quantity in hospitals around the country and
 18 they are being used in the emergency room, on
 19 the general floor, in the operating room, and
 20 they are circulating through various
 21 environments.

22 I was involved with the central
 23 processing supply team that looked at means to
 24 clean and disinfect those pumps once they come
 25 out of the patient arena, areas. And that's

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2 probably kind of answering the question that
 3 you have for me.

4 Q. Before I ask you if you could tell
 5 us about that, is that the only example that
 6 you can think of where you were involved in
 7 developing a cleaning protocol for either an
 8 operating room or the equipment in it?

9 A. At the cardiovascular room in
 10 St. Luke's Episcopal Hospital and Texas Heart
 11 Institute, the amount of equipment in those
 12 cardiovascular rooms in volume is tremendously
 13 large and the cleaning that needs to be taking
 14 place between patient use is very important.
 15 I was part of the panel that reviewed. I
 16 don't think that I wrote procedures or
 17 protocol how to, but I did participate in
 18 determination of what agents and when it
 19 should be used and how to use it on medical
 20 devices.

21 Q. Was that type of determination also
 22 something you were involved with with respect
 23 to the infusion pumps?

24 A. Correct.

25 Q. Which agents in either situation

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2 were selected, do you recall?

3 A. No, I don't recall because they
 4 have brand name, germicide -- germicide or --
 5 they have a specific brand name at the time
 6 that were picked up, and I don't remember.

7 Q. And do you remember what the
 8 chemicals were, separate from the brand names?

9 A. Those were agents that were -- that
 10 are able to penetrate biofilm and kill
 11 bacteria. I don't remember the names.

12 Q. Were these agents for use on the
 13 outside of medical equipment or on the inside
 14 of medical equipment?

15 A. By a majority, they were on the
 16 outside. However, some equipment like the
 17 warming/cooling circulating device in
 18 cardiovascular operating room has tanks that
 19 you have accessibility to the inside of their
 20 container, so it was used inside as well.

21 Q. Were you part of determining the
 22 cleaning protocol for the heater/cooler units?

23 A. I was part of the team. I wouldn't
 24 say that I determined how it should be done,
 25 but I was part of the team and my expertise

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2 came from the biomedical engineering, for
 3 example, to make sure that the agent is not
 4 damaging the equipment.

5 Q. With respect to hoses used in
 6 operating rooms, that would be an important
 7 consideration, right? Not damaging the
 8 equipment with the cleaning agent?

9 A. Right.

10 Q. Were you involved in determining
 11 the interval of cleaning for any of the
 12 equipment you've identified?

13 A. I would bring my recommendation
 14 after I consulted with the manufacturers on
 15 that, so we will present specific scenario.
 16 That's how many patients a day we expect this
 17 device to be used on, these are the agents we
 18 would like to use, and this is the process we
 19 will use them. And I would expect the
 20 manufacturer to tell me what will be the
 21 impact on the device.

22 Q. So once the team you were working
 23 on -- let me just make sure I understood that.
 24 The team you were working with would determine
 25 what they would wish to do and then consult

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2 with the manufacturer to see if that would be
 3 posing a risk on device integrity? Is that
 4 what you said?

5 A. That would be a fair conclusion,
 6 yes.

7 Q. Okay. I'm sorry, I meant within --
 8 within the team, did you have expertise that
 9 was being drawn upon with respect to the
 10 interval for cleaning?

11 A. I don't think so.

12 Q. Okay. Do you know how the team
 13 went about validating -- was it part of the
 14 team effort to validate particular agents to
 15 see if they would be effective?

16 A. Yes. There was a trial period of
 17 an agent being used and there were specific
 18 observation on different part of the cleaning
 19 material. Like if you mentioned hoses, there
 20 would be a descriptor of how to review
 21 possible changes in the physical performance,
 22 physical present -- appearance of the hose.

23 If there is polyvinyl somewhere
 24 that is more flexible, if they are metal -- I
 25 was very concerned about labeling. I was

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2 concerned that a warning and labeling and how
 3 to increase or decrease power on something
 4 will not be visible after a while, so all
 5 those were put into a testing periodicity with
 6 observation being collected.

7 Q. Do you have any familiarity with
 8 the tests that were conducted to determine
 9 kill-off of bacteria and whether that was
 10 sufficient?

11 A. In the example I gave you, no.

12 Q. Were you ever a person who provided
 13 expert advice about how to determine if a
 14 cleaning agent was killing sufficient
 15 bacteria?

16 A. I would refer to the expert on
 17 that.

18 Q. And that would not be you?

19 A. It will not be me.

20 Q. Are you familiar with the concept
 21 of a sterile device?

22 A. Yes.

23 Q. All devices are not sterile. Is
 24 that correct?

25 A. That is a correct statement.

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2 Q. The operating room contains many
 3 devices that are not sterile. Is that
 4 correct?

5 A. That is correct.

6 Q. Would you agree that air is not
 7 sterile?

8 A. Depends where.

9 Q. In an operating room?

10 A. I will agree with that.

11 Q. Will you agree that people are not
 12 sterile?

13 A. You mean as producing offspring or
 14 as --

15 Q. Ha. No. I mean as producing
 16 contamination, bacteria. Or containing.

17 A. I agree with that, yes.

18 Q. A surgeon, after scrubbing, for
 19 example, is not sterile, correct?

20 A. The surgeon himself is not. The
 21 outside layer, it is.

22 Q. The outside layer of what?

23 A. Of what the surgeon has on him.

24 Q. Do you believe that the surgeon's
 25 clothing is sterile?

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2 A. Yes.

3 Q. Do you believe it remains sterile
 4 once it's outside the package?

5 A. I see what you're saying. It's a
 6 good point. I agree with it.

7 Q. I think the record is confused.

8 Once the surgeon's clothes are out
 9 of their packaging and on the surgeon, are
 10 they sterile?

11 A. They are still sterile until they
 12 either touch or impinge a nonsterile object.

13 Q. And in normal use in an operating
 14 room, would you expect the surgeon's clothes
 15 to become contaminated to some degree?

16 MR. BANKSTON: Object to the form.

17 A. You're taking me to an area that I
 18 didn't study, so I cannot respond to the
 19 question.

20 BY MS. EATON:

21 Q. After prepping, do you believe a
 22 patient is sterile?

23 A. The area that was prepped, yes.

24 Q. What definition do you have of
 25 sterile?

<p style="text-align: center;">Page 222</p> <p>1 Y. DAVID</p> <p>2 A. I'll have to look it up.</p> <p>3 Q. Okay. Do you have in mind, as you</p> <p>4 sit here today, any particular definition of</p> <p>5 sterility?</p> <p>6 A. Free from pathogen above certain</p> <p>7 level.</p> <p>8 Q. Okay. And do you know what that</p> <p>9 level is?</p> <p>10 A. Just by heart, no.</p> <p>11 Q. Okay. Is that a standard that you</p> <p>12 ever applied, that you were the expert</p> <p>13 applying?</p> <p>14 A. No. It's not something that I</p> <p>15 applied.</p> <p>16 Q. Would you agree that an operating</p> <p>17 room doesn't have to be sterile in order to</p> <p>18 proceed with surgery?</p> <p>19 A. That is a difficult statement to</p> <p>20 take because not being sterile have different</p> <p>21 level of dirtiness to it. So I don't think</p> <p>22 that a filthy operating room is appropriate.</p> <p>23 Q. Did your job ever involve</p> <p>24 determining what standard of pathogenic</p> <p>25 organisms could be in an operating room for it</p>	<p style="text-align: center;">Page 223</p> <p>1 Y. DAVID</p> <p>2 to be acceptable?</p> <p>3 A. No, not my area of expertise.</p> <p>4 Q. Are there people, to your</p> <p>5 understanding, in hospitals who do address</p> <p>6 that?</p> <p>7 A. Yes.</p> <p>8 Q. Do those people address the levels</p> <p>9 of contamination that can be present on</p> <p>10 surfaces in the operating room?</p> <p>11 A. I have no knowledge of their</p> <p>12 standards.</p> <p>13 Q. Okay. In your experience, are</p> <p>14 operating room floors cleaned?</p> <p>15 A. "Cleaned" is an open-ended word and</p> <p>16 I agree with it, yes.</p> <p>17 Q. Are practices taken to clean</p> <p>18 operating room floors in the hospitals that</p> <p>19 you've worked in?</p> <p>20 A. I didn't understand the question.</p> <p>21 Q. Do people take steps to clean</p> <p>22 operating room floors in the hospitals you've</p> <p>23 worked in?</p> <p>24 A. Oh, yeah, sure.</p> <p>25 Q. How frequently have the floors been</p>
<p style="text-align: center;">Page 224</p> <p>1 Y. DAVID</p> <p>2 cleaned, to your observation, in the hospitals</p> <p>3 you've worked in, in operating rooms?</p> <p>4 A. Every day.</p> <p>5 Q. How many times a day?</p> <p>6 A. Depends on the designation of the</p> <p>7 operating room.</p> <p>8 Q. What about an operating room where</p> <p>9 orthopedic surgery would take place? How many</p> <p>10 times a day?</p> <p>11 A. They will clean it between uses.</p> <p>12 Q. Does that mean between every</p> <p>13 surgery?</p> <p>14 A. Between every orthopedic</p> <p>15 procedures, yes.</p> <p>16 Q. Do you know what cleaning agents</p> <p>17 are used on the floor?</p> <p>18 A. No.</p> <p>19 Q. Do you know if the standards for</p> <p>20 cleaning -- I'm sorry. Do you know if the</p> <p>21 cleaning agents used on the floor for</p> <p>22 orthopedic surgeries at the hospitals where</p> <p>23 you've worked changed at all during the time</p> <p>24 you worked there?</p> <p>25 A. Yes.</p>	<p style="text-align: center;">Page 225</p> <p>1 Y. DAVID</p> <p>2 Q. Do you know what chemical they were</p> <p>3 changed from or to?</p> <p>4 A. No, but as I was working in those</p> <p>5 orthopedics operating room, I could see</p> <p>6 different colors and different smells at times</p> <p>7 as they were cleaning the floors and I was</p> <p>8 working on the equipment.</p> <p>9 Q. Have you ever seen an orthopedic</p> <p>10 surgery in process?</p> <p>11 A. Oh, yeah.</p> <p>12 Q. Are drills and saws used during</p> <p>13 that surgery?</p> <p>14 A. It is like a spare parts garage.</p> <p>15 Tools, hammers, drills, saws, a variety of</p> <p>16 implants. As a matter of fact, it might shock</p> <p>17 some lay people to see how much physical</p> <p>18 activity is taking place there.</p> <p>19 Q. When those saws or drills or other</p> <p>20 equipment are used -- I'm sorry, let me ask a</p> <p>21 better question.</p> <p>22 Is some of that equipment we just</p> <p>23 talked about electrical equipment?</p> <p>24 A. Yeah. Some is air-driven,</p> <p>25 pressured air. Some are electrical driven.</p>

<p>1 Y. DAVID</p> <p>2 Q. When those pieces of equipment are</p> <p>3 used in orthopedic surgery, do they cause the</p> <p>4 release of particles into the air?</p> <p>5 A. They do.</p> <p>6 Q. You can see them?</p> <p>7 A. At times you can see them.</p> <p>8 Q. Do those devices, any of them, blow</p> <p>9 air?</p> <p>10 A. I don't know if I would call it</p> <p>11 blowing air. They have electrical connections</p> <p>12 and they might be driven by pressured air that</p> <p>13 would spin a turbine, but I'm not sure that</p> <p>14 they are blowing outside.</p> <p>15 Q. That's a good distinction. So some</p> <p>16 of -- which pieces of equipment are you</p> <p>17 thinking of that are driven by turbines?</p> <p>18 A. There are drills that are using air</p> <p>19 as compared to saws that are using electric</p> <p>20 power.</p> <p>21 Q. Do the saws have a cooling fan for</p> <p>22 the electrical component?</p> <p>23 A. No. The circulating nurse usually</p> <p>24 will use fluid to cool the area and all that</p> <p>25 will go down the floor.</p>	<p>1 Y. DAVID</p> <p>2 Q. Have you ever become aware of any</p> <p>3 test or comparison of the volume or quantity</p> <p>4 or type of particles emitted from various</p> <p>5 equipment used in an operating room?</p> <p>6 A. No. I don't believe that I was</p> <p>7 involved in such study.</p> <p>8 Q. Are you aware of any FDA regulation</p> <p>9 requiring there to be a filter on a patient</p> <p>10 warming device?</p> <p>11 A. I'm not aware of an FDA regulation</p> <p>12 that states that the filter must be part of</p> <p>13 the design. The FDA does not get into the</p> <p>14 design details but rather the performance and</p> <p>15 the operation of the total system. I'm aware</p> <p>16 of the desire to comply with safe deployment</p> <p>17 of equipment in the operating room, and if</p> <p>18 filter is one mechanism to make this device</p> <p>19 safe, then there should be a filter there.</p> <p>20 Q. Separate from the general</p> <p>21 considerations that you just set forth, are</p> <p>22 you aware of any specific standard that has</p> <p>23 been issued or adopted by FDA regulation that</p> <p>24 would require a filter on a patient warming</p> <p>25 device?</p>
<p>1 Page 228</p> <p>2 Y. DAVID</p> <p>3 MR. BANKSTON: Object to the form.</p> <p>4 A. I don't believe that the FDA's role</p> <p>5 is to determine how technology is being</p> <p>6 designed and delivered to clinical site. The</p> <p>7 FDA is, rather, looking at, as much as they</p> <p>8 can, at the product features and risk, the</p> <p>9 same way that the FDA doesn't say that you</p> <p>10 have to have a red light or a long handle to</p> <p>11 hold a device.</p> <p>12 But if that's part of the features,</p> <p>13 then there is a reason to look and see what</p> <p>14 this feature does to the safe operation of the</p> <p>15 device.</p> <p>16 BY MS. EATON:</p> <p>17 Q. Are you familiar with the process</p> <p>18 by which FDA establishes special controls for</p> <p>19 certain class 2 devices?</p> <p>20 A. Yes.</p> <p>21 Q. As part of that process, does FDA</p> <p>22 ever adopt specific standards for either a</p> <p>23 device or a test that might be used with a</p> <p>24 device?</p> <p>25 A. There are a few standards that the</p> <p>FDA recognized and adopted, especially in the</p>	<p>1 Page 229</p> <p>2 Y. DAVID</p> <p>3 cardiovascular arena.</p> <p>4 Q. Have you looked at the</p> <p>5 classification regulation for patient warming</p> <p>6 devices?</p> <p>7 A. Yes.</p> <p>8 Q. Does it include any special</p> <p>9 controls?</p> <p>10 A. No.</p> <p>11 Q. Are you familiar with any industry</p> <p>12 standard that guides the design or manufacture</p> <p>13 of patient warming devices?</p> <p>14 A. Except the good manufacturing</p> <p>15 practice, no.</p> <p>16 Q. Are you aware of any hospital</p> <p>17 standard that requires filters to be present</p> <p>18 on specific patient warming devices?</p> <p>19 A. No, I'm not aware.</p> <p>20 Q. Are you familiar with the</p> <p>21 ventilation requirements -- I'm sorry, let me</p> <p>22 ask that differently.</p> <p>23 Are you responsible for evaluating</p> <p>24 or implementing the ventilation requirements</p> <p>25 for hospital operating rooms?</p> <p>A. As we discussed this morning, my</p>

<p>1 Y. DAVID 2 involvement -- my involvement in operating 3 room design and function has evolved over the 4 years and especially here in Texas Medical 5 Center. The hospital I worked with, I have a 6 responsibility for equipment planning and it 7 was in the facility design I would be part of 8 the operating room design team and I would be 9 part of the room air exchanges, temperature 10 controls, humidity -- 11 Q. Thank you. I had forgotten that. 12 You did say that this morning. 13 Would part of your role involve 14 evaluating or selecting filtration for 15 operating room air? 16 A. No. I would not select the 17 filters. 18 Q. Do you have any expertise in 19 filters? 20 A. Expertise? I understand their 21 function and their construction, how they are 22 rated, how they're being measured, so I have 23 working knowledge of filters and filters' 24 functionality. 25 Q. That working knowledge, was that</p>	<p>1 Y. DAVID 2 developed in connection with this case? 3 A. I believe that I described several 4 times today that it's been much beyond that. 5 In the areas of operating room design, cardiac 6 catheterization room design, I was involved 7 with probably 50 or 60 of those facilities and 8 equipment planning and discussion about 9 filtration and filters were part of the team 10 discussion. 11 I did not select filters, as I said 12 before, but that's where my working knowledge 13 comes from. 14 Q. Have you ever conducted testing of 15 a filter, any kind of testing of a filter? 16 A. I don't believe that I did. 17 Q. Have any of your work 18 responsibilities outside of litigation 19 involved filtration on medical devices 20 specifically as opposed to rooms? 21 A. The examples that come to my mind 22 as we sit here today are involvements that I 23 have with mechanical ventilators and bedside 24 monitors. Those two product categories 25 involve both protection of the device from</p>
<p>1 Y. DAVID 2 penetration of bacteria from the outside as 3 well as protection of the device from 4 developing pathogens in the internal cavities. 5 Q. In what context have you worked 6 with those two devices? 7 A. With the ventilators, I was invited 8 to travel to Travemünde in Germany. That's 9 where Dräger Medical is located and doing 10 their research and manufacturing, and they 11 were developing a new pediatric ventilator and 12 wanted to have an opinion about how the 13 clinicians and the biomedical engineers and 14 the hospital will review their product 15 features. 16 So they took the medical director 17 of the neonatology ICU, a respiratory 18 therapist director and myself, and we were 19 participating in brainstorming session that 20 looked at how the device is going to be 21 maintained, its cleanliness, in face of some 22 challenging environment, challenging in regard 23 to pathogens. 24 The other example involved bedside 25 monitoring, and on that product I was invited</p>	<p>1 Y. DAVID 2 to Redmond, Washington, to visit with Space 3 Lab company who developed a new colored 4 monitor for vital signs to be used in 5 intensive care units and wanted to know if the 6 feature of interaction with the display by 7 physically have a touch-sensitive display are 8 appropriate for the environment as to where 9 the monitor will be versus where the operating 10 will be and will -- filter changes will be 11 technically challenged if you have to do so 12 many steps to get to the filters. 13 Q. For either one of those examples, 14 were you providing any type of microbiology or 15 infectious disease expertise? 16 A. No. 17 Q. Have you ever tested filters for 18 efficiency at capturing particles? 19 A. No. 20 Q. Has part of your professional 21 responsibility outside of litigation ever 22 involved interpreting filter efficiency 23 testing? 24 A. I believe that during the project 25 that involved the trace amount of anesthetic</p>

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2 gases in the operating room, we had part of
 3 our measurement the air combination level by
 4 changing the number of room air exchanges over
 5 a certain range in looking for the outcome as
 6 well as by changing filters.

7 Q. Were you providing expertise with
 8 respect to the filters and their effect on the
 9 air?

10 A. No. I was part of the team that
 11 has -- my part was different role.

12 Q. Are you familiar with the MERV,
 13 M-E-R-V, rating system for filters?

14 A. Yes.

15 Q. Are you familiar with that outside
 16 of your work on this case? Had you been
 17 familiar with that outside of your work on
 18 this case?

19 A. Yes. And MERV is an abbreviation,
 20 as you know.

21 Q. Is that something you used in your
 22 work outside of this case or encountered?

23 A. Encountered. I'm not sure that I'm
 24 using it.

25 Q. Have you seen indication that the

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2 filter for the model 750 Bair Hugger device
 3 meets MERV 14 standards?

4 A. There is test results within the
 5 documents that I have here of testing that
 6 filter efficiency. But as I sit here, I don't
 7 recall by heart what level of MERV that would
 8 be.

9 Q. Do you have any opinion about what
 10 the particle capture efficiency of any Bair
 11 Hugger filter is separate from a document that
 12 you've reviewed in one of the binders sitting
 13 in front of you?

14 A. I don't believe that I understand
 15 your question.

16 Q. Do you have any information about
 17 the efficiency of a Bair Hugger filter
 18 separate from the documents that are sitting
 19 here in front of you?

20 A. Separate, no.

21 Q. Have you reviewed any hospital
 22 infection rates or records with respect to
 23 Bair Hugger use in connection -- I'm sorry,
 24 with -- let me ask a better question.

25 Have you reviewed any hospital

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2 infection rates or records that you've
 3 attempted to correlate in any way to Bair
 4 Hugger use?

5 A. Well, my report includes a
 6 significant amount of literature on that, and
 7 I read that and drew a conclusion.

8 Q. Separate from the literature listed
 9 in your report, have you reviewed any?

10 A. Separate? I don't think so.

11 Q. Have you taken any action to try to
 12 remove Bair Hugger devices from any hospitals?

13 A. I have no authority to do that.

14 Q. Have you communicated to any
 15 hospital a concern about Bair Hugger use or a
 16 belief that they should take action?

17 A. No.

18 Q. Do you know if St. Luke's or Texas
 19 Children's Hospitals continue to use Bair
 20 Hugger devices?

21 A. I do not know.

22 Q. Have you contacted anyone at the
 23 FDA or the CDC with respect to the Bair Hugger
 24 device?

25 A. No.

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2 Q. Do you know anyone who has had a
 3 surgery where a Bair Hugger device was used?

4 A. I don't believe that I know that.

5 Q. Do you know of any individual
 6 person who's had an infection after a Bair
 7 Hugger device was used?

8 A. Outside the --

9 Q. Information that's --

10 A. -- government study?

11 Q. Outside the information that you
 12 reviewed for this case.

13 A. No.

14 Q. Have you spoken with anyone other
 15 than plaintiffs' lawyers about the Bair Hugger
 16 device and its potential -- I'm sorry -- let
 17 me ask a better question.

18 Have you spoken with anyone other
 19 than plaintiffs' lawyers about the Bair Hugger
 20 device causing infections, in your opinion?

21 A. No.

22 Q. Have you spoken with anyone who you
 23 believe to be the treating physician for any
 24 plaintiff?

25 A. No.

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1 Y. DAVID

2 Q. Have you spoken to any healthcare
 3 facilities where you believe any of the
 4 plaintiffs in this litigation have had their
 5 surgeries performed?

6 A. I have no knowledge where it was
 7 performed.

8 Q. Have you watched the "green smoke"
 9 video prepared by Scott Augustine?

10 A. As I said earlier today, I watched
 11 a video, YouTube video, that Dr. Augustine
 12 prepared. I don't know if it was green or
 13 yellow, something. He has something there
 14 that I watched. I don't know what it was.

15 Q. Do you have any information about
 16 that test beyond what's available from viewing
 17 the YouTube video?

18 A. No.

19 Q. Did you make any inquiry into the
 20 conditions, for example, of how that test was
 21 conducted?

22 A. No.

23 Q. Does that test in any way form the
 24 basis for your opinions in this case?

25 A. Not at all.

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2 Q. Have you ever reviewed the
 3 deposition transcripts of any of the study
 4 authors that are cited in your report with
 5 respect to studies about the Bair Hugger
 6 device?

7 A. Can you ask that again?

8 Q. Your report includes a citation to
 9 several articles with respect to the Bair
 10 Hugger device. Have you reviewed the
 11 deposition transcripts of any of those
 12 authors?

13 A. I wasn't aware that they were
 14 deposited, so no, I did not.

15 Q. Do you have any information that
 16 any of the authors on those studies have tried
 17 to culture bacteria coming out of a Bair
 18 Hugger system used with a blanket attached?

19 A. I do not have information on those
 20 studies except what's in the publication.

21 Q. If Dr. McGovern, for example, had
 22 tried to culture bacteria coming out of a Bair
 23 Hugger system when operated with a blanket
 24 attached and was not able to do that, would
 25 that be important to you?

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1 Y. DAVID

2 MR. BANKSTON: Object to the form.

3 A. I read his study. It was a large
 4 population, close -- I think over 1500 total
 5 cases. It was well executed. I don't think
 6 that I made comments to myself about trying to
 7 swab in the Bair Hugger itself. I don't
 8 recall that in the study.

9 BY MS. EATON:

10 Q. And do you recall anything in the
 11 study report saying, "We made tests to look
 12 for live bacteria in the room or in the air
 13 after the Bair Hugger was used"? Did you
 14 recall any results like that in the paper?

15 A. As you marked the evidence today,
 16 there are 11 binders here with material. I'm
 17 afraid I have to tell you that I cannot
 18 remember the study unless you give me time to
 19 read it.

20 Q. We might do that in a moment.
 21 Would it be important to you if there were
 22 tests made to determine if live bacteria came
 23 out of the Bair Hugger blanket when the system
 24 was operated as it was intended to be used?
 25 Whether those results were positive or

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1 Y. DAVID

2 negative, would that be important to you?

3 A. Well, my report points to two
 4 mechanisms for increasing infection risk at
 5 the surgical site when Bair Hugger is used.
 6 One is the thriving of pathogens from the
 7 floor device. The other one is the
 8 interruption of unidirectional flow around the
 9 surgical site due to conduction of warm air --
 10 warm air eddies.

11 So that may be one of the
 12 mechanisms, but there's another mechanism
 13 that's contributing to the Bair Hugger
 14 contribution to risk threat that you're not
 15 addressing.

16 Q. Would it be important to you with
 17 respect to the first mechanism that you
 18 identified if air was cultured after the Bair
 19 Hugger device was operated as a system with a
 20 blanket attached and there were no live
 21 bacteria?

22 MR. BANKSTON: Object to the form.

23 A. I believe it would be, but as I
 24 said, there are two mechanisms. This is one
 25 of the two. And there are other studies that

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1 Y. DAVID

2 suggest that there were contamination in a
 3 large number of Bair Huggers that were
 4 studies. The Stanford study, for example, is
 5 one of them.

6 BY MS. EATON:

7 Q. Are you pointing to any study where
 8 the Bair Hugger device was operated as a
 9 system with its blanket and live bacteria
 10 were cultured in high levels in the air after
 11 that?

12 MR. BANKSTON: Object to the form.

13 A. No. I'm referring to culturing the
 14 Bair Huggers.

15 BY MS. EATON:

16 Q. You mean taking swabs from the
 17 inside of the units?

18 A. From the hose.

19 Q. In your hospital, were hoses used
 20 directly on patients without blankets
 21 attached?

22 A. I don't believe so.

23 Q. From your review of the operating
 24 instructions in this case, are you aware that
 25 that would be in violation of the

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1 Y. DAVID

2 instructions?

3 A. I'm not suggesting that that's how
 4 the Bair Hugger is being used. I'm suggesting
 5 that the hose that has positive culture is
 6 connected to a blanket, so if they identify
 7 positive culture at the end of the hose that's
 8 connected to the blanket, they can probably
 9 measure positive culture if they would do it
 10 on the blanket as well.

11 Q. Do you know how much air force it
 12 would take to remove bacteria from the inside
 13 of a hose?

14 A. No.

15 Q. Have you identified any patient
 16 warming device that does not have a hose that
 17 runs between the unit and a blanket and serves
 18 as a connector?

19 A. Sure. All the conductive warming
 20 devices that use pads and have no air
 21 circulated whatsoever.

22 Q. There's no connection between the
 23 pad and any hardware unit?

24 A. There is. There's no hose.

25 Q. Okay. Thank you.

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1 Y. DAVID

2 A. Can we have a break?

3 MR. BANKSTON: Yeah, we've been
 4 going over an hour and a half.

5 MS. EATON: Have we?

6 MR. BANKSTON: Yeah.

7 MR. GOSS: One hour.

8 MS. EATON: Okay. It doesn't seem
 9 that long to me.

10 MR. BANKSTON: The room is a little
 11 stuffy and we have an older witness. If
 12 he wants a break, I'd like to give it.

13 MS. EATON: That's fine.

14 THE VIDEOGRAPHER: We're going off
 15 the record at 16:33.

16 (Recess, 4:33 p.m. to 4:54 p.m.)

17 THE VIDEOGRAPHER: We are back on
 18 the record at 16:54.

19 BY MS. EATON:

20 Q. Dr. David, do you have any
 21 expertise in aerobiology?

22 A. I don't believe so.

23 Q. Have you ever tested the
 24 effectiveness of any laminar flow system?

25 A. No, I did not.

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1 Y. DAVID

2 Q. Do you have any expertise in air
 3 flow or air movement?

4 A. Expertise, I have a very good
 5 working knowledge being in orthopedics
 6 operating room, being in the cardiovascular
 7 operating room, in general in large
 8 concentration of operating room at the Texas
 9 Medical Center. I'm talking about 60 to 65
 10 operating rooms and be responsible for all the
 11 medical technologies in that area. I fully
 12 understand what the unidirectional flow in a
 13 protective area is all about. I fully
 14 understand design of operating room, of
 15 cardiac catheterization laboratory that I was
 16 involved with and the placement of objects
 17 within that environment.

18 So I have a very good working
 19 knowledge and I can explain to a layperson
 20 about it, but I don't believe that I'm expert
 21 in that area.

22 Q. Do you have any expertise in
 23 infectious disease?

24 A. No, I do not.

25 Q. Do you have any expertise in

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 2 surgical site infections?
 3 A. No, I do not.
 4 Q. Do you have any expertise in
 5 aseptic technique?
 6 A. Again, I have good working
 7 knowledge because this would be part of my
 8 involvement in equipment that is present
 9 during surgical procedures and in trauma rooms
 10 and I will be required to oblige by techniques
 11 such as that.
 12 Q. Is our earlier discussion today
 13 reflective of your involvement in those
 14 matters?
 15 A. It was a specific example. My
 16 involvement is much wider because I would be
 17 walking literally daily through the operating
 18 theater, visiting with the director of the
 19 operating room, visiting with surgeons, and
 20 looking at the various devices that are being
 21 used. So I have intimate interaction with
 22 that area.
 23 Q. Do you have responsibility -- I'm
 24 sorry, let me ask it differently.
 25 Have you had responsibility within

1 Y. DAVID
 2 hospitals for implementing infection control
 3 practices?
 4 A. I do not believe that I have the
 5 expertise in implementing infection control
 6 practices, but as it involves equipment in
 7 areas that might have risk of infections and
 8 contamination such as intensive care unit and
 9 moving ventilators and infusion pumps from one
 10 room to another, I have been involved with a
 11 team that would implement that type of
 12 practice.
 13 Q. Are you a medical doctor?
 14 A. No, I'm not a medical doctor.
 15 Q. Do you have any medical training?
 16 A. I do not have medical training.
 17 Q. Do you have expertise in heat
 18 transfer?
 19 A. Being a biomedical engineer, it was
 20 one of the courses that I took as part of my
 21 academic preparation. Heat transfer is an
 22 important physical phenomenon, and I studied
 23 and understand it. And I understand the
 24 principle operation.
 25 Q. You mentioned radiant heat earlier.

1 Y. DAVID
 2 Is that one form of heat transfer?
 3 A. Absolutely.
 4 Q. Is conductive heat another form of
 5 transfer?
 6 A. Correct.
 7 Q. And is convective heat another form
 8 of transfer?
 9 A. Like ovens, yes.
 10 Q. Have you ever participated in an
 11 infectious disease outbreak investigation?
 12 A. Yes.
 13 Q. How many times?
 14 A. Couple of times.
 15 Q. For which hospital?
 16 A. I'm not sure that I can discuss
 17 that. There might be some protective order
 18 there.
 19 Q. Okay. Was that in connection --
 20 well, was that in connection with litigation?
 21 A. No.
 22 Q. Both times you can remember, were
 23 they at the same hospital?
 24 A. Yes, I believe the same hospital.
 25 Q. Do you recall what the organism was

1 Y. DAVID
 2 ultimately that was at issue?
 3 A. No, I do not.
 4 Q. What was your role in the
 5 investigation?
 6 A. As the team investigate --
 7 investigated the possible source and
 8 contributing factors, my role was to ascertain
 9 the functionality of the medical devices in
 10 it.
 11 Q. Were any patient warming devices
 12 involved? Let me ask a different question.
 13 Did you investigate any patient
 14 warming devices?
 15 A. Yes, we did. We had the
 16 fluid-circulating devices at the time and they
 17 were part of the investigation.
 18 Q. What kind of fluid-circulating
 19 device?
 20 A. I can see the product in front of
 21 me. I don't remember the brand name.
 22 Q. Was it the -- I did not -- I'm
 23 sorry. I didn't -- do you recall the function
 24 of the device separate from the brand name?
 25 A. Yes. The device would heat fluids

<p>1 Y. DAVID 2 and circulate it through a mattress under the 3 patient. So it would be a conduction heat. 4 Q. Were other sources in the operating 5 room considered as well? 6 A. Yes. 7 Q. Can you give me examples of the 8 other kinds of sources that were considered? 9 A. Ventilators, mechanical ventilator. 10 Q. Anything else? 11 A. No. 12 Q. From the outset there was a focus 13 on those two pieces of equipment? 14 A. No. I'm just not -- feel 15 comfortable to discuss that. 16 Q. Okay. Let me -- you're concerned 17 about confidentiality, is that it? Or what do 18 you mean by "not comfortable"?. 19 A. Yes. 20 Q. Okay. I don't want to violate your 21 confidentiality. That's not what I'm seeking 22 to do. 23 Are you familiar with the 24 principles of outbreak investigation through 25 your work?</p>	<p>1 Y. DAVID 2 A. Yes. 3 Q. Is there any standard that you use 4 or refer to? 5 A. As one member on the team, there 6 were other experts that that seemed to be 7 their field of expertise, so we were given the 8 protocol and the plan of action. 9 Q. Does one aspect of investigation 10 when there's a concern about an outbreak 11 involve taking cultures and swabs from various 12 locations, for example? 13 A. Absolutely. 14 Q. Would that include surfaces within 15 the room? 16 A. Yes. 17 Q. Would it include surfaces that are, 18 for example, a countertop or a wall or a 19 floor? 20 A. Yes. 21 Q. Would it include testing -- I'm 22 sorry. Would it include taking samples or 23 swabs from medical equipment that is in the 24 room? 25 A. Yes.</p>
<p>1 Page 252 2 Y. DAVID 3 Q. What other types of steps would be 4 involved in an infectious disease outbreak in 5 a hospital setting? 6 A. The steps it will involve will be 7 identifying the pathogen, see if it can be 8 matched with patient -- with a result of 9 patient testing, and begin to eliminate 10 potential sources. 11 Q. Do you try to do that investigation 12 as close as possible in time to when a 13 surgical operation may have occurred? 14 A. It's an interesting question. 15 However, I believe that those areas were not 16 surgical areas. 17 Q. Okay. Are you familiar with the 18 process used for doing an outbreak 19 investigation when the area at issue is an 20 operating room? 21 A. I would say it's a similar process. 22 Q. Okay. Are you a certified 23 industrial hygienist? 24 A. No, I'm not. 25 Q. Have you ever published anything in peer-reviewed literature concerning what does</p>	<p>1 Page 253 2 Y. DAVID 3 or does not cause surgical site infections? 4 A. No, I did not. 5 Q. Are you aware -- actually, let me 6 just take that back. I'm going to mark -- 7 (Discussion off the stenographic 8 record.) 9 (David Exhibit 12 marked.) 10 BY MS. EATON: 11 Q. This is a June 1, 2000 letter that 12 I believe you've reviewed. Is that correct? 13 (Document review by witness.) 14 BY MS. EATON: 15 Q. Have you seen this before? 16 A. Yes. 17 Q. Okay. If you would look at the 18 fourth paragraph, please. 19 A. Okay. 20 Q. The last sentence in that paragraph 21 says, "With this amendment, the filters in our 22 currently cleared devices (including the SE 23 Device Model 505) and the Model 750, will all 24 be 0.2-micron filters." 25 Do you see that sentence? A. Yes.</p>

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2 Q. Does anything about this letter
 3 describe to the FDA what efficiency of capture
 4 at the .2-micron size the filter will have?

5 A. Well, the second paragraph is
 6 saying that the air filter described is HEPA
 7 filter in their submission and that was the
 8 plan. But due to certain accessibility to
 9 material, that filter is not available.

10 However, we know that it's not just
 11 the filter but also the pressure drop that was
 12 difficult for the 750.

13 Q. Maybe my question wasn't clear.
 14 I'm asking if there's anything about this
 15 letter --

16 A. And --

17 Q. -- that you take -- were you going
 18 to get to the question?

19 A. Yes.

20 Q. Okay.

21 A. So I'm trying to answer your
 22 question by saying that, first of all, there
 23 is indication that HEPA filter is there and
 24 there is no change from filter
 25 characteristics. Paragraph 2 and 3 are saying

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2 that. And paragraph 3 is saying it will be
 3 2.2-micron, so the impression is, is .2-micron
 4 with same efficiency, when one reads this
 5 letter.

6 Q. Are you aware of anyplace in this
 7 letter or otherwise where any company made a
 8 representation to the FDA about what
 9 percentage capture of particulates of
 10 the .2-micron size a Bair Hugger filter would
 11 have?

12 A. I believe when you called a filter
 13 a HEPA, high-efficiency particle arrestor, you
 14 are designating the efficiency of 99.97% --

15 Q. Is it your interpretation of
 16 this --

17 A. -- at .2 micron.

18 So when you read this letter, you
 19 are getting the impression that that's the
 20 area we are addressing, that level of
 21 efficiency.

22 Q. You read this letter to be the
 23 company telling the FDA that the Bair Hugger
 24 devices will have a HEPA filter? That's how
 25 you read this letter?

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1 Y. DAVID

2 A. No. I'm saying that the
 3 preliminary paragraph, it's simply, look, the
 4 first paragraph saying we have submission and
 5 we would like to amend it. The second
 6 paragraph's saying we talked about HEPA filter
 7 and we're going to get something that is
 8 similar. The third paragraph said, I cannot
 9 get this but it will be similar
 10 characteristics. The last line on the third
 11 paragraph specifically says we want to have
 12 the option to use our current filter
 13 characteristics, and then they go to
 14 the .2 micron without any additional
 15 description.

16 So if it's different than that, why
 17 don't you say it's different? If it's the
 18 same, then that's what you started the letter
 19 with.

20 Q. So you believe that the second
 21 paragraph in this letter says to you that the
 22 existing filters on the Bair Hugger devices
 23 are HEPA filters?

24 MR. BANKSTON: Objection to form.

25 A. I believe that what I'm saying is

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1 Y. DAVID

2 that it will be the same as the SE device as
 3 the 500 series, which was close to HEPA.
 4 BY MS. EATON:

5 Q. Where in this letter does it say
 6 the 500 series filter was close to HEPA?

7 A. Where? I have 10 binders here we
 8 marked up with information saying that that's
 9 the filter in the 500 series.

10 Q. A HEPA filter?

11 MR. BANKSTON: Object to the form.

12 A. I didn't say HEPA.

13 BY MS. EATON:

14 Q. I'm trying to understand what
 15 you're saying because what you're saying is
 16 not appearing to me in this letter. Are you
 17 saying you have all these binders --

18 A. No problem.

19 Q. -- of material that say that the
 20 filter in the 505 was close to HEPA?

21 A. Right. The drop from M10 to M20, I
 22 think they called it, specific brand, is
 23 significant drop in efficiency. But what I'm
 24 saying is the material I have here is saying
 25 that the 505 filter has 90% efficiency

<p>1 Y. DAVID 2 at .2-micron, and the 750 submission was 3 saying we're going to have much higher flow 4 rate and we're going to have a better filter, 5 it will be HEPA filter. But then a week 6 later, hey, listen, Mr. FDA, I cannot get it 7 but I'll get something that is similar to what 8 the 500 is. 9 The 500 is 90% efficiency. It 10 doesn't say here that .2-micron would have 50% 11 or less efficiency as it came out to be. 12 Q. So if we would look at the letter 13 that is in front of you, the paragraph that I 14 first referred to, the fourth paragraph, 15 begins by saying, "We want to amend the 510(k) 16 to include a filter that is substantially 17 equivalent to the filter currently being used 18 in all of our cleared devices." 19 Do you see that sentence? 20 A. Yes. 21 Q. Okay. With respect to the 22 "currently" -- I'm sorry. With respect to the 23 filter that was being used in 500 series 24 devices, is there anywhere you can point me to 25 that the company told the FDA what percentage</p>	<p>1 Y. DAVID 2 efficiency that filter would have at 3 a .2-micron level? 4 A. I'll be happy to do that. I can 5 start looking at the material. 6 Q. Well, I don't want to take the time 7 to have you look at material, so I'm just -- 8 let me ask this differently. 9 MR. BANKSTON: Object to the form. 10 BY MS. EATON: 11 Q. If the FDA wished to take action 12 against the company for its filter, what 13 percentage efficiency at the .2-micron level 14 would be the threshold below which there would 15 be a problem? 16 A. If you're saying at the third 17 paragraph that we have option to use the 18 current filter characteristics and you're 19 saying in the fourth paragraph it will be a 20 substantial equivalent to the filter currently 21 being used on all our cleared devices, that is 22 a clear indication that we're going to use a 23 filter that is better than 90% efficient 24 at .2-micron. That's not what happened after 25 this letter.</p>
<p>Page 260</p> <p>1 Y. DAVID 2 Q. Was the efficiency of capture at 3 a .2-micron level a design input for this 4 product? 5 A. I believe design input was a HEPA 6 filter to begin with, so it was better than 7 that. 8 Q. Let's look at the 500 series. Was 9 efficiency of capture of a percentage 10 at .2-micron-size particle part of the design 11 input for the 500 series products? 12 A. I did not see the design input 13 characteristics. I saw the outcome, and the 14 outcome is a filter that has better than 90% 15 efficiency at .2-micron. 16 Q. Was the capture efficiency 17 at .2-micron a specification in the 510(k) 18 submission for the 500 series devices? 19 A. I don't understand what you mean by 20 "specification." It is a feature of the 21 system. 22 Q. Okay. There is a sentence in this 23 document that says, "The change to add the 24 filter with the SE" -- let me ask this 25 differently.</p>	<p>Page 261</p> <p>1 Y. DAVID 2 When would -- what percentage 3 reduction in capture of particles at 4 the .2-micron size would result in a filter no 5 longer being substantially equivalent? 6 A. Excellent question. I would love 7 to see a study that would answer that. We 8 don't have one. 9 Q. What information would you need to 10 know that you don't know? 11 A. A clinical study in operating room 12 that do orthopedic surgery with such a filter 13 conducted by infectious disease expert. 14 Q. Okay. 15 (Sotto voce discussion.) 16 BY MS. EATON: 17 Q. Are you aware of any -- let me say 18 this differently. Are you aware of any 19 clinical data that establishes a different 20 infection risk based on filter characteristics 21 for a Bair Hugger device? 22 A. I don't believe that as I sit here 23 today I'm prepared to tell you that I'm aware 24 of -- I can search for it, because what I am 25 aware of is that the large amount of</p>

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2 publication are talking specifically about the
 3 relationship between filter effectiveness and
 4 increased threat of surgical site infection.

5 And as a matter of fact, we have
 6 standards, and in this case I have a policy
 7 example from M.D. Anderson, a well-known
 8 hospital, that are saying that we have to have
 9 filters with HEPA efficiency in those
 10 protective environment where the threat of
 11 infection in orthopedic surgery is higher than
 12 in other locations.

13 So I'm not here sitting today and
 14 can point to here's the study. I can do my
 15 homework and find it for you. But I'm saying
 16 that the ample data that I am providing here
 17 to you today is suggesting that the less
 18 efficient the filter is, the higher the threat
 19 of infection at the surgical site. There's a
 20 simple relationship.

21 Q. What study, in your mind -- are you
 22 able to cite me to a single study, sitting
 23 here today, that would establish what you just
 24 said?

25 MR. BANKSTON: Object to the form.

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2 A. Counsel, this is an excellent
 3 question and I think that the manufacturer of
 4 a device who has filters in such environment
 5 should do the study and bring the solution,
 6 bring the answer. If the solution is there's
 7 no difference, use the filter that has only
 8 70%. If the solution is, oh, my God, this is
 9 real problem, you better change the filter or
 10 change the product. But that's exactly where
 11 we are today is that we do not have a properly
 12 conducted double-blind study of infection
 13 rates in orthopedic surgeries where
 14 air-warming -- forced-air warming devices were
 15 used and it should be done if a manufacturer
 16 is considered to be prudent and care for
 17 patient safety.

18 Q. What size are the bacteria that
 19 cause surgical site infections?

20 A. Look. I have Dr. Hogg's paper here
 21 and it has an exact size. You want the
 22 viruses that are smaller than 1 microns, you
 23 have bacteria between 1 and 6 microns, fungi
 24 is above that. We can go back and forth about
 25 how much I remember of all this material, but

1 Y. DAVID

2 A. In the McGovern study, they have
 3 the Bair Hugger and when they removed it and
 4 used another patient warming device, there was
 5 81% reduction in infection. With the Bair
 6 Hugger, there was 3.8 index increased
 7 probability of infection.

8 At the incident with the literature
 9 review that I cited in my report, looking at
 10 all the studies, the conclusion was simple
 11 that a HEPA filter is one of the ways to
 12 mitigate infection. The CDC article that I
 13 have in my publication also talks about
 14 filtering level efficiency. They -- the
 15 literature from orthopedics, Bone & Joint
 16 Journal, is talking about one of the solution
 17 is increase filter efficiency.

18 So there's ample evidence out there
 19 that there is a relationship between filter
 20 efficiency and the potential risk of infection
 21 at the surgical site.

22 BY MS. EATON:

23 Q. Would a 75% capture of .2-micron
 24 particles change the clinical risk as opposed
 25 to a 90% capture of .2-micron particles?

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2 this information is today in the public
 3 domain. I don't have to be expert about that.

4 Q. But I do want to understand what
 5 your expertise is. Did you mean Dr. Ho?

6 A. Ho, yeah.

7 Q. Have you reviewed his report?

8 A. Report, I've reviewed -- it's in my
 9 report here, I've reviewed it --

10 Q. I don't believe it is. I don't
 11 think it would have even been available to you
 12 at the time you prepared your report, but
 13 you've mentioned his name more than once. And
 14 so I --

15 A. Okay, so I take your word for it.
 16 I learned about it after I wrote my report.

17 Q. Well, one thing we have -- there
 18 have been several times today when you've
 19 mentioned either transcripts or reports that
 20 you believe you've reviewed that are not in
 21 front of us, and I -- Mr. Ulatowski is one I
 22 know for sure; I do believe in the morning
 23 Dr. Ho may have been another.

24 Is there someplace you can check
 25 for me to determine if you have some

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2 additional materials that you have reviewed
 3 that are maybe not here today?

4 A. There's no additional material. We
 5 covered that subject totally. Ulatowski is
 6 one that is missing here. It will be added to
 7 the -- Dr. Ho, maybe it was after my report
 8 was written.

9 Q. I'm just wanting to make sure I
 10 understand all the materials you've reviewed.
 11 So if there's a place where you're -- could
 12 you take a look when you return to your home
 13 or office and just see if there perhaps are
 14 other materials that you have reviewed?

15 A. I certainly can do this, Counsel,
 16 and I will be happy to oblige. I can tell you
 17 that I made an effort to have all the material
 18 here today with us and I believe it is, except
 19 Tim Ulatowski.

20 Q. Okay. Sitting here today for
 21 purposes -- let me ask that differently.

22 For purposes of coming to your
 23 opinions in this case, did you rely on any
 24 understanding about what size bacteria cause
 25 surgical site infections?

1 Y. DAVID

2 A. For arriving at my opinion in this
 3 case, I fully appreciate the difference in
 4 sizes and the intensity of bioburdens of
 5 viruses, bacteria, fungi, as it relates to
 6 surgical site infection. I did not use that
 7 to arrive at my opinion. My opinions are
 8 biomedical engineering and risk assessment
 9 based.

10 Q. In assessing the risk that a
 11 difference in filtration at .2-micron size
 12 makes, what did you consult?

13 A. I consulted the literature, the
 14 medical and scientific literature, and I
 15 consulted the responses to answers by the
 16 defendant officers to a specific question
 17 about this subject.

18 Q. And are all the materials that
 19 you've just referenced identified in your
 20 report?

21 A. Absolutely.

22 Q. Okay. Did you conduct a literature
 23 search yourself?

24 A. The literature that I present in my
 25 report are a combination of my search and

1 Y. DAVID

2 counsel providing me with some.

3 Q. Are you able to tell me which items
 4 were provided by counsel?

5 A. Specifically which ones, no, I
 6 don't.

7 Q. And if you would open up, please,
 8 the binder that has literature in it just so
 9 that we could take a look at the specific
 10 index, whichever binder that is. I think it
 11 may be the one in your hand, I don't know.
 12 No? Sorry.

13 A. This is the one.

14 Q. Okay. Just see if by taking a look
 15 at that list you can identify any items that
 16 you believe were provided by counsel.

17 A. I would say that all those that has
 18 a numerical number at the end, 3MBH, a number
 19 that no question provided to me by counsel.

20 Q. Anything else?

21 (Document review by witness.)

22 A. I don't remember exactly, but some
 23 title like Forced Air Warming Blower
 24 Evaluation would be a title that I would come
 25 up and search and ask.

1 Y. DAVID

2 BY MS. EATON:

3 Q. Could I see the binder for one
 4 moment?

5 A. (Complies.)

6 Q. Thank you, sir.

7 What search terms did you use --
 8 I'm sorry, let me ask that differently.
 9 What -- tell me about the search you
 10 conducted.

11 A. Well, I went on PubMed and visited
 12 the Texas Medical Center library and looked at
 13 mostly forced-air warming devices, and if
 14 there is something about filter efficacy. So
 15 this study is talking about evaluation,
 16 probably I picked it up in my search.

17 Q. Okay. Do you recall or did you
 18 record anywhere what search terms you used?

19 A. What search terms? No, I did not
 20 record that.

21 Q. Do you recall how many articles
 22 came back in response to your search terms?

23 A. Not really, no.

24 Q. Did you review the abstracts for
 25 all articles that came back in response to the

1 Y. DAVID
 2 search terms you used?
 3 A. If it got late at night, I probably
 4 did not read all the abstracts but I made an
 5 effort to go through them and request those
 6 that I seemed to think applicable. I have --
 7 I remember reading abstract from "Anesthesia,"
 8 the journal, that looks like something I would
 9 like to have, but it ended up that the
 10 abstract was not really useful for me.
 11 Q. What -- did you have any
 12 prespecified criteria for what an article
 13 needed to have before it would be one you
 14 would consider relevant?
 15 A. No.
 16 Q. What was your research question?
 17 A. I'm not sure that I have research
 18 question.
 19 Q. What was your -- what kind of
 20 article were you looking for?
 21 A. I was looking for a comparative
 22 article, article that would have a good
 23 research design, hopefully similar
 24 environment, large population, and
 25 peer-reviewed.

1 Y. DAVID
 2 Q. Okay. What would it be comparing,
 3 what to what?
 4 A. I wanted to see. I didn't have a
 5 pre-notion about what should be there.
 6 Q. What were you looking to find out
 7 from these articles?
 8 A. The level of knowledge within the
 9 professional community of the relationship
 10 between forced-air warming devices and
 11 surgical infection during orthopedic surgery;
 12 the possible methods that are used to identify
 13 that; the span of instrumental devices that
 14 are mentioned in those articles. That's about
 15 it.
 16 Q. Okay. Are you familiar with the
 17 term "systematic literature review"?

18 A. Yes.
 19 Q. That's not what you conducted.
 20 A. Correct.
 21 Q. Would you agree?
 22 A. Correct.
 23 (Sotto voce discussion.)
 24 MS. EATON: What time is left on
 25 the record?

1 Y. DAVID
 2 THE REPORTER: We're at 6:17 right
 3 now.
 4 MR. BANKSTON: Let's go off the
 5 record for just one second.
 6 (Discussion off the stenographic
 7 record.)
 8 THE VIDEOGRAPHER: We're going off
 9 the record at 17:36.
 10 (Recess, 5:36 p.m. to 5:37 p.m.)
 11 THE VIDEOGRAPHER: We're back on
 12 the record at 17- -- wait a minute.
 13 We're back on the record at 17:37.
 14 BY MS. EATON:
 15 Q. When you reviewed the literature,
 16 did you locate any articles that evaluated
 17 whether the use of the Bair Hugger device
 18 increased the risk of infection and found that
 19 it did not?
 20 A. Just to make sure that I understand
 21 your question, you're saying the article
 22 talked about increased infection but the
 23 conclusion or the finding was that it was not?
 24 Q. Yes, that the test question was
 25 whether it would increase the risk of

1 Y. DAVID
 2 infection and it did not.
 3 A. I don't think so.
 4 Q. Did you locate any articles that
 5 concluded specifically that the Bair Hugger
 6 device decreased the risk of surgical site
 7 infection?
 8 (Document review by witness.)
 9 A. One of the articles that I indicate
 10 and consider is the review article of existing
 11 literature by Wood, Moss and Keenan, and I'm
 12 not sure, I need to read the study again, but
 13 maybe one of the articles there was saying
 14 there was no difference. I don't think that
 15 there was decrease, but no difference. I just
 16 need to read that paper again.
 17 BY MS. EATON:
 18 Q. If there were articles that
 19 established that the -- I'm sorry. If there
 20 were articles that reported that the use of a
 21 forced-air warming device during surgery
 22 decreased the risk of surgical site infection,
 23 would that be relevant to your consideration?
 24 A. It would.
 25 Q. If there were articles

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1 Y. DAVID

2 demonstrating that there were no clinically
 3 significant increases in particle count with
 4 the use of a Bair Hugger or forced-air warming
 5 device, would that be relevant to your
 6 opinions?

7 A. It would. But again, Counsel, you
 8 remember that I incorporate into my opinion
 9 two routes. Two routes. The particle count
 10 is one way to increase the threat of infection
 11 but there is the heat itself --

12 Q. Yes.

13 A. -- as another path.

14 Q. And if you had located any article
 15 that would demonstrate the use of a Bair
 16 Hugger device did not interfere with laminar
 17 flow, would that be relevant to your opinions?

18 A. Yes.

19 Q. Have you been provided with any of
 20 the reports of defense experts in this case,
 21 other than potentially Dr. Ho?

22 A. Outside what I have here, no. I
 23 don't have anything that was not included.

24 Q. When you were selecting articles to
 25 include in your report, did you specifically

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1 Y. DAVID

2 select only those that had a conclusion that
 3 supported your opinion that the Bair Hugger
 4 device has the potential to increase infection
 5 risk?

6 A. That's a nice gentle way to suggest
 7 that I preselected the articles, but no, I
 8 select articles based on the concept of the
 9 use of forced warm air device and infection.
 10 So those that I have in my report are the
 11 articles that they came back.

12 Q. So if there are articles that would
 13 not support an inclusion -- if there are
 14 articles that would not support a conclusion
 15 that the Bair Hugger device might increase
 16 surgical site infection risk, they're not
 17 included because you didn't find them?

18 MR. BANKSTON: Object to the form.

19 A. I -- I don't know if there are
 20 studies of quality and peer-review journal
 21 that suggest what you're saying, but if there
 22 are, I would like to read them.

23 BY MS. EATON:

24 Q. Are you familiar with an article
 25 with the first author Kurz, K-U-R-Z?

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1 Y. DAVID

2 A. What's the title of the article?

3 Q. I am not sure by heart. I have it.

4 THE VIDEOGRAPHER: Christin, I
 5 think your mic popped off. It only goes
 6 so far.

7 MS. EATON: Sorry.

8 THE VIDEOGRAPHER: That's okay.

9 MS. EATON: Thank you for letting
 10 me know.

11 BY MS. EATON:

12 Q. "Perioperative Normothermia to
 13 Reduce the Incidence of Surgical-Wound
 14 Infection and Shorten Hospitalization."

15 A. The heading doesn't seem like
 16 something that would fall within my search.

17 Q. Does that mean you believe you did
 18 or didn't see this article?

19 A. That probably I did not see it.

20 Q. Okay. Why would it not fall within
 21 your search?

22 A. Because I provided you the route I
 23 took to look specifically at engineering,
 24 biomedical engineering type of information
 25 relating to infection and this type of patient

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1 Y. DAVID

2 warming device. So what you are pointing at
 3 probably would not come in my search. Would
 4 not come up in my search.

5 Q. Thank you for that clarification.

6 Did you make any attempt to assess
 7 the clinical benefit that may be provided by
 8 normothermia in any respect?

9 A. I believe that the benefit is
 10 discussed in many studies. I don't have to go
 11 into these clinical issues.

12 Q. Do you dispute that the maintenance
 13 of normothermia or the prevention of
 14 hypothermia results in clinical benefit?

15 A. For specific patient conditions, I
 16 do not.

17 Q. Is there a surgical -- okay, let me
 18 say that differently.

19 You're familiar that one of the
 20 recommended infection control practices for
 21 surgery is to maintain normothermia?

22 MR. BANKSTON: Object to the form.

23 A. Yes, Counsel, but I believe we
 24 talked about cooling down patients during a
 25 cardiovascular procedure and bypass of the

<p>Page 278</p> <p>1 Y. DAVID 2 heart where specifically you're cooling down 3 patients. I don't believe you want to 4 maintain normothermia in those patients. So I 5 agree with you that certain patient conditions 6 would -- seems to benefit from normothermia, 7 but not all patients. 8 BY MS. EATON: 9 Q. Setting aside cardiovascular 10 surgery, any other surgery that you would 11 separate out? 12 A. I'll have to think about it. I did 13 not prepare myself to respond to that. 14 Q. Did you make any investigation 15 related to evaluating the potential infection 16 reduction that could result from the use of 17 forced-air warming? 18 A. I believe you're asking me a 19 clinical question that was not my objective. 20 Q. Did you make any evaluation of the 21 clinical -- okay, let me say that differently. 22 What do you mean by that, what you 23 just said? 24 MR. BANKSTON: Object to the form. 25 A. What I mean by that is simply that</p>	<p>Page 279</p> <p>1 Y. DAVID 2 my charge was to look at the Bair Hugger 750 3 from hazard and risk control issues, not from 4 clinical outcomes, the type of question you 5 have for me. 6 BY MS. EATON: 7 Q. Okay. So making a medical 8 causation determination is not something that 9 you set out to do. 10 A. Medical causation is not -- what I 11 am prepared to do is to offer the opinion that 12 the Bair Hugger 750, when it is operating in 13 orthopedic surgical procedures, more likely 14 than not will contribute to a higher risk of 15 surgical site infection. 16 Q. Than what? 17 A. More likely than not. 18 Q. As compared to what? I may have 19 misunderstood you. 20 A. I don't think that I compared it 21 to. 22 Q. Let me read the answer. 23 (Counsel reviewing realtime 24 transcript on the reporter's computer.) 25 --oOo--</p>
<p>Page 280</p> <p>1 Y. DAVID 2 BY MS. EATON: 3 Q. Will contribute a higher risk than 4 if it were not used? 5 A. Correct. 6 Q. Is the interpretation of clinical 7 study data about infection risk something that 8 you have ever done outside of your work in a 9 lawsuit? 10 A. Can you ask it again? 11 Q. Outside of your work for a lawsuit, 12 is the interpretation of clinical study data 13 concerning infection risk something that you 14 do? 15 A. In my work, I'm expected to read 16 clinical literature and scientific 17 publication. I am educated, trained, and have 18 the experience to understand the study 19 structure and the strength of the conclusions. 20 And in my evaluation of various 21 medical devices, at the hospital I worked for 22 for over 25, 30 years, part of the process was 23 to review current medical and scientific 24 literature relating to device performance and 25 bring that to what in my report describe as</p>	<p>Page 281</p> <p>1 Y. DAVID 2 MTEC, M-T-E-C, Medical Technology Evaluation 3 Committee, that looked at the overall what you 4 asked earlier, benefit-to-risk ratios and 5 understand what the product risk based on the 6 information from the manufacturers, but also 7 based on experience that comes from clinical 8 studies that published in peer-reviewed 9 journals. 10 Q. If the use of a forced-air warming 11 device decreases infection risk, would that be 12 relevant to a clinical benefit-risk 13 assessment? 14 A. Yes. 15 Q. Okay. In your work -- well, you -- 16 have you ever -- more probable than not, is 17 that a scientific standard? 18 A. Yes. 19 Q. Okay. Is there anyplace in an 20 engineering standard that you say more 21 probable than not is the criteria? 22 A. Many times. 23 Q. Can you identify one? 24 A. Can I make a joke in a casino? 25 Yes. For example, when the Space</p>

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1 Y. DAVID

2 Shuttle Challenger disaster happened, I
 3 followed clearly -- sorry. I followed
 4 intimately the investigation because I wanted
 5 to see what they are doing relating to
 6 discovery of risk, and one of the team members
 7 were talking about more probably than not,
 8 this part was subjected to cold temperature
 9 below the span of specification.

10 So yes, it's a nonengineering term.

11 Q. In terms of making a comparison of
 12 the likelihood that one patient warming device
 13 would change the infection risk as compared to
 14 another patient warming device, have you
 15 included in your report everything that you
 16 reviewed?

17 A. Yes.

18 Q. Is there any clinical data you're
 19 aware of that would suggest there's a
 20 difference in infection risk between the Bair
 21 Hugger device and any other patient warming
 22 device that you have identified in your
 23 report?

24 A. I didn't find it, so everything
 25 that I did is in my report.

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1 Y. DAVID

2 A. Underlying data? I've read the
 3 article. I understand how it was conducted,
 4 how the data was collected. If there's
 5 something beyond the study information, no, I
 6 don't know.

7 Q. Have you ever taken any course in
 8 epidemiology or biostatistics?

9 A. I don't think that I have
 10 epidemiology courses. I had the courses in
 11 engineering about statistics.

12 Q. Do you consider yourself an expert
 13 in biostatistics?

14 A. No, I'm not.

15 Q. Okay. Do you consider yourself an
 16 expert in epidemiology?

17 A. No, I'm not.

18 Q. Okay. Do you have any familiarity
 19 with the concept of confounding as it might
 20 impact study results?

21 A. I'm familiar with the concept, yes.

22 Q. Okay. Did you make any evaluation
 23 of the McGovern study and how they did or did
 24 not attempt to control for confounding?

25 A. I read that. I think that the

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1 Y. DAVID

2 Q. Did you find any studies that
 3 suggested the risk was not different between
 4 the Bair Hugger device and another type of
 5 patient warming device?

6 A. No, I did not.

7 Q. Did you look?

8 A. I believe that I did look and the
 9 literature did not have a simultaneously
 10 double-blind study with two different
 11 products. What they come close to is what I
 12 have here, was the McGovern, of removing the
 13 Bair Hugger and using something else. And
 14 it's clearly -- a clear indication of the
 15 improvement in the rate of infection when the
 16 Bair Hugger was not there.

17 Q. Yet you didn't put the HotDog
 18 device in your report, right?

19 MR. BANKSTON: Object to the form.
 20 BY MS. EATON:

21 Q. We can move on because that's
 22 already established.

23 Are you aware of any information
 24 about the underlying data from the McGovern
 25 study?

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1 Y. DAVID

2 conclusions were important for me and the
 3 study contained large enough population to be
 4 significant and published in peer-reviewed
 5 journal.

6 Q. And would you agree with the
 7 authors of the McGovern study that this study
 8 does not establish a causal basis for an
 9 association between the type of warming device
 10 and infection risk?

11 A. I read that part, yes.

12 Q. And do you agree with it?

13 A. I agree with their conclusions,
 14 yes.

15 Q. Why did that part not make it into
 16 your report?

17 MR. BANKSTON: Object to the form.

18 A. I beg a difference with you because
 19 the study is included. My report is having
 20 the take-home comments from myself.

21 BY MS. EATON:

22 Q. Did every single article that you
 23 reviewed include a similar statement that the
 24 study did not establish a causal association
 25 between use of the Bair Hugger device and an

<p style="text-align: center;">Page 286</p> <p>1 Y. DAVID 2 increase in infection risk? 3 A. I don't believe I followed your 4 question. 5 MS. EATON: Could you read that 6 back? 7 (The reporter read back the 8 following portion of the preceding 9 record.) 10 "QUESTION: Did every single 11 article that you reviewed include a 12 similar statement that the study did not 13 establish a causal association between 14 use of the Bair Hugger device and an 15 increase in infection risk?" 16 (End of readback.) 17 A. I understand the comment you're 18 making. The studies that I read are 19 specifically concluding with measurements and 20 effect of what they found out relating to the 21 device, Bair Hugger. So that was my focus and 22 interest to know as far as the risk associated 23 with that. 24 If there is a comment about not 25 having association, that -- that left that for</p>	<p style="text-align: center;">Page 287</p> <p>1 Y. DAVID 2 the clinician. 3 BY MS. EATON: 4 Q. And if the authors of a study said 5 that their study did not establish that the 6 Bair Hugger device or a forced-air warming 7 device caused an increase in infection, would 8 you defer to them on that? 9 A. I would defer to them, yes. 10 MS. EATON: What is my record time? 11 THE REPORTER: 6:40, ma'am. 12 BY MS. EATON: 13 Q. Okay. With respect to the 14 potential modifications to the Bair Hugger 15 device identified on pages 35 to 37 of your 16 report, do you have any information beyond 17 what you have included in your report about 18 the feasibility of these alternatives? 19 A. These alternatives represent a very 20 significant effort by 3M engineers to explore 21 different solution to the problem that we are 22 discussing here today. The feasibility looks 23 to me to be within the reasonable range 24 with... 25 (Document review by witness.)</p>
<p style="text-align: center;">Page 288</p> <p>1 Y. DAVID 2 BY MS. EATON: 3 Q. I'm just asking you if you have 4 anything beyond what you've put in your 5 report. 6 A. No. 7 Q. Are you aware that any of these 8 designs have ever been implemented by 3M or 9 any other company? 10 A. My understanding, they have not. 11 The management refused to implement them. 12 Q. Is it your understanding that 13 prototypes were developed that would have been 14 workable in practice? 15 A. My understanding that some of the 16 alternatives represented in these pages became 17 a prototype. 18 Q. Is your understanding based only on 19 the materials that you've reviewed in this 20 case? 21 A. Correct. 22 Q. Were you provided with the 23 deposition of Winston Tan? 24 A. If it's not noted in my report, I 25 did not. I was not.</p>	<p style="text-align: center;">Page 289</p> <p>1 Y. DAVID 2 Q. What data establishes that any of 3 the alternative products identified in your 4 report are safer than the Bair Hugger device? 5 A. That's an excellent question, and I 6 believe that I address that. Because as I'm 7 looking at alternative design, I'm describing 8 three paths. One is to add something to the 9 product. The other one is to remove, or a 10 third way, to re-engineer the device in a 11 different way. These devices that I mention 12 are in several different physical principles 13 of operation. Conductions, convective, and 14 no forced air at all but rather using 15 electrical pad is one of the criteria that I 16 just mentioned. 17 So if you have articles that I 18 mention in my report that are suggesting that 19 removal of the Bair Hugger reduce infections 20 by 81% like McGovern is saying, or the 21 potential for cultures will be dropped like 22 the Stanford study is saying with cleaning or 23 removing of those products, then changing from 24 forced air open-ended through perforation of 25 the blanket to recirculated air to HEPA filter</p>

<p>1 Y. DAVID 2 with warning to a non-air-use electric pads to 3 a nonmoving blanket with much smaller air flow 4 rate that does not disturb the unidirectional 5 flow in the operating room, all provide for 6 significant improvement in smaller amount of 7 risk exposure and uninterrupted 8 unidirectional flow in the OR. Those are two 9 principles that I described in my report.</p> <p>10 Q. Are you an expert in the 11 relationship between particles and bacteria or 12 infection risk?</p> <p>13 A. Expert in the relationship between 14 particle and bacteria. While I do not 15 understand your question, I don't pretend to 16 be expert in relationship between particle and 17 bacteria.</p> <p>18 Q. Okay. Did you look for any 19 clinical data on any of the three devices 20 identified in your report that might indicate 21 their performance or infection risk?</p> <p>22 A. The literature support my argument. 23 Even 3M that bought Vital Health, in their 24 disclosure to a press release saying that this 25 is safe and effective device and would</p>	<p>1 Y. DAVID 2 supplement the product that they have. And 3 when you do not have warm air circulating but 4 it's a closed loop, I don't think that you 5 need to be an expert to realize that you're 6 removing a threat. You therefore are reducing 7 exposure to the risk.</p> <p>8 Q. Are you familiar with the concept 9 that direct contact with a surface can pose an 10 infection risk?</p> <p>11 A. That makes sense.</p> <p>12 Q. Is that something that you're 13 familiar with in your work in the hospitals?</p> <p>14 A. Well, hand hygiene is a typical 15 example. Very, very known in hospitals.</p> <p>16 Q. And reusable medical equipment that 17 directly touches patients, that's also an 18 example?</p> <p>19 A. Well, it's not the same because 20 most of the accessories that will touch 21 patients will be disposable, single use, and 22 probably sterile. So that's not the same as 23 hands touching surfaces.</p> <p>24 Q. Have you provided in your report 25 all of the data that you reviewed with respect</p>
<p>1 Y. DAVID 2 to the alternative products that you've 3 identified?</p> <p>4 A. Yes, I did.</p> <p>5 MS. EATON: Do I have any time 6 left?</p> <p>7 THE REPORTER: You're at 6:48.</p> <p>8 MS. EATON: Okay. I'm going to 9 reserve.</p> <p>10 MR. BANKSTON: Yeah, I'm a little 11 hot so we'll take a literally two- or 12 three-minute break.</p> <p>13 THE VIDEOGRAPHER: We're going off 14 the record at 18:08.</p> <p>15 (Recess, 6:08 p.m. to 6:17 p.m.)</p> <p>16 THE VIDEOGRAPHER: We are back on 17 the record at 18:17.</p> <p>18 EXAMINATION</p> <p>19 BY MR. BANKSTON:</p> <p>20 Q. Dr. David, you were asked some 21 questions about risk-benefit. Do you remember 22 those questions?</p> <p>23 A. I do.</p> <p>24 Q. Okay. First of all, is it your 25 opinion that the Bair Hugger should be taken</p>	<p>1 Y. DAVID 2 out of rooms and not replaced with any form of 3 patient warming?</p> <p>4 A. No.</p> <p>5 Q. Okay. Are there other devices 6 available, other design concepts which are 7 feasible to be made without the same risk 8 mechanism that you identified in your report?</p> <p>9 MS. EATON: Object to the form of 10 the question.</p> <p>11 A. Right. I indicated in my report 12 and so is my opinion that I identify specific 13 product with different features that remove 14 the risk introduced by the Bair Hugger 750 and 15 yet serve the purpose of controlling patient 16 temperature environment.</p> <p>17 BY MR. BANKSTON:</p> <p>18 Q. Does the literature you reviewed 19 contain any studies or any opinions concerning 20 whether any of these devices are similar in 21 effectiveness to the Bair Hugger at 22 maintaining patient temperature?</p> <p>23 A. I was trying to scan in my memory 24 where that might be in my report.</p> <p>25 Q. Let me know.</p>

<p style="text-align: center;">Page 294</p> <p>1 Y. DAVID 2 A. And I think that -- 3 Q. Well, can I direct you to a page 4 maybe that I want to ask you about? 5 A. In the -- 6 Q. Let me withdraw that -- let me 7 withdraw that question, Dr. David. Can we 8 take a look at your report? Can you flip to 9 page 39 for me? 10 MS. EATON: And I'll just object to 11 this as leading. 12 MR. BANKSTON: Okay. 13 BY MR. BANKSTON: 14 Q. Do you see a reference on 39 to 15 Dr. Daniel Sessler? 16 A. Yeah, that's the one I was looking 17 for, actually. 18 Q. Who is Dr. Daniel Sessler? What 19 role does he play? 20 A. I understand that he was or is 21 clinical consultant to 3M and might be working 22 with other vendors. 23 Q. Did you rely on Dr. Sessler's 24 opinions in any respect in this case? 25 A. Well, one thing that his study was</p>	<p style="text-align: center;">Page 295</p> <p>1 Y. DAVID 2 supportive is that resistant heating 3 mattresses are of equal efficiency to the Bair 4 Hugger forced-air blanket in maintaining 5 temperature, and that's why I incorporate that 6 study here. 7 Q. Okay. From your engineering 8 background and experience, do you have any 9 opinion on whether, apart from these four 10 devices, just from an engineering concept 11 standpoint, is it possible, more likely than 12 not, to design a device that does not pose the 13 risks you've identified but warms patients as 14 effectively? 15 MS. EATON: Object to the form of 16 the question. 17 A. These devices that I show as 18 alternatives are demonstrating that. 3M 19 engineers have several concepts that they came 20 up with. One of them is the, I believe, 21 recirculating, is basically what I have in my 22 alternative design, so it is feasible. 23 BY MR. BANKSTON: 24 Q. Okay. You were asked some 25 questions about speaking to hospitals about</p>
<p style="text-align: center;">Page 296</p> <p>1 Y. DAVID 2 Bair Hugger risk. Do you remember those 3 questions? 4 A. Yes. 5 Q. Okay. When you began work on this 6 case, did you sign a protective order? 7 A. I did. 8 Q. Okay. Did you review confidential 9 materials in this case? 10 A. I did. 11 Q. Did you rely on any confidential 12 materials in coming to your conclusions in 13 this case? 14 A. Yes. 15 Q. Do you have any understanding of 16 what will happen to you if you disclose 3M's 17 confidential information in the things you've 18 learned in this case? 19 A. I understand, and that's part why I 20 didn't discuss that with hospitals. 21 Q. You take those obligations 22 seriously in terms of protecting 3M's 23 corporate property? 24 A. I do. 25 Q. When you, in your career, have been</p>	<p style="text-align: center;">Page 297</p> <p>1 Y. DAVID 2 evaluating medical devices for healthcare 3 facilities, did you come to any understandings 4 during those days regarding whether certain 5 procedures had unique vulnerabilities to 6 infection? 7 MS. EATON: Object to the form of 8 the question. 9 A. There is no question that after so 10 many years in the largest medical center in 11 the country, as I worked in, you get exposed 12 to condition of patients from A to Z and there 13 are variation. There are patients that come 14 in with sore throat and would go home. There 15 are patients that come in with a brain tumor 16 and it will be very difficult to deal with 17 that. 18 So there are environments that are 19 much more susceptible to condition that the 20 patients are in than others, and specifically 21 orthopedic surgery is one of those 22 environments. 23 BY MR. BANKSTON: 24 Q. I would like to show you a document 25 that's been previously marked in this</p>

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1 Y. DAVID
 2 litigation as Exhibit 47. Can you take a look
 3 at that document for me?
 4 MS. EATON: Can you tell me what
 5 you're looking at?
 6 MR. BANKSTON: Why don't you take a
 7 look at it before he does. Should be
 8 able to -- it's a 510(k) summary of the
 9 505 series.
 10 MS. EATON: Thank you.
 11 BY MR. BANKSTON:
 12 Q. Dr. David, this is a document you
 13 reviewed and relied on in this case?
 14 MS. EATON: Objection to the form.
 15 A. Yes.
 16 BY MR. BANKSTON:
 17 Q. Okay. Can you take a look at the
 18 second page there?
 19 A. Okay.
 20 Q. Do you see a spot on there where
 21 the highlight is on filter density?
 22 MS. EATON: Objection to the form.
 23 A. Yes, I do.
 24 BY MR. BANKSTON:
 25 Q. Okay. Can you explain why filter

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1 Y. DAVID
 2 density was important to you in terms of this
 3 document?
 4 MS. EATON: Objection to the form.
 5 A. Filter density is one of the
 6 characteristics describing the filter features
 7 and it is important because the less dense
 8 filter will be less efficient.
 9 BY MR. BANKSTON:
 10 Q. In this document, in this 510(k)
 11 application or summary, whatever the word you
 12 want to use for it is, are two Bair Hugger
 13 devices being described and their filter
 14 density?
 15 A. Correct.
 16 MS. EATON: Objection to the form.
 17 BY MR. BANKSTON:
 18 Q. Did you gain any understanding from
 19 this document whether the 500 series Bair
 20 Hugger and the 505 series Bair Hugger have the
 21 same filter density?
 22 A. That's what this document is
 23 suggesting.
 24 Q. Do you know, sitting here today,
 25 whether these --

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1 Y. DAVID
 2 MS. EATON: Just let me interject
 3 an objection to the form.
 4 BY MR. BANKSTON:
 5 Q. Do you know sitting here today
 6 whether the 700 series has the same filter
 7 density as the 500 series?
 8 A. I know that it does not. It has
 9 less efficient.
 10 Q. Okay. Thank you, Dr. David. Let's
 11 put that back in your book so we don't lose
 12 it.
 13 Dr. David, you were asked about
 14 another document today in your materials
 15 section. It has been previously marked in
 16 this litigation as Exhibit 48 [Exhibit 12].
 17 You remember this letter?
 18 MS. EATON: Is this the one we
 19 previously discussed?
 20 MR. BANKSTON: This is the one you
 21 offered into evidence, yes.
 22 MS. EATON: I didn't offer it into
 23 evidence, just to be clear. I asked him
 24 to look at it.
 25 MR. BANKSTON: Oh, I'm sorry, I

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1 Y. DAVID
 2 didn't know that you didn't offer it
 3 into evidence. I thought everything
 4 that was marked was going into evidence
 5 on the books. Is that not what we're --
 6 we're not going to put all the materials
 7 in?
 8 MS. EATON: I'm certainly not aware
 9 of any protocol for offering anything
 10 into evidence. I simply asked him to
 11 review something.
 12 MR. BANKSTON: All right. Let's go
 13 ahead -- no, actually, that's previously
 14 marked so I don't mind.
 15 BY MR. BANKSTON:
 16 Q. Dr. David, I'm showing you what's
 17 been marked previously in this litigation as
 18 Exhibit 48 [Exhibit 12]. Do you remember
 19 discussing this letter today?
 20 A. Yes.
 21 Q. Okay. Do different filters have
 22 different characteristics or do all filters
 23 have the same characteristics?
 24 A. Oh, no. There's a wide span in
 25 different characteristics between the filters.

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1 Y. DAVID

2 Q. Is the efficiency of a filter one
3 of its characteristics?

4 A. Very important characteristic.

5 Q. If a device manufacturer reduced
6 the filtration efficiency of one of its
7 filters but told the FDA that we'd still be
8 using, quote, "our current filter
9 characteristics," is that honest?10 MS. EATON: Objection to the form,
11 foundation.

12 A. That is absolutely misleading.

13 BY MR. BANKSTON:

14 Q. Okay. If you knew or had been
15 exposed to articles discussing a decrease in
16 surgical site infection in certain procedures
17 such as, say, a colorectal surgery, would that
18 have any application to your opinions
19 regarding the risk of infection in orthopedic
20 surgeries?

21 MS. EATON: Objection to the form.

22 A. I feel that the orthopedic
23 surgeries are a specific area of surgical
24 procedures. They are longer, they are more
25 complex. They are more susceptible to

Page 304

1 Y. DAVID

2 models of the Bair Hugger?

3 A. Yes.

4 Q. Okay. If there are articles out
5 there discussing bacterial sampling with a
6 previous model 500 series instead of a model
7 700 series, can you tell me if or if not that
8 would have any direct engineering application
9 to your opinions about the model 700 series in
10 this case?

11 MS. EATON: Objection to the form.

12 A. It's very important because the
13 features of those two families of product, the
14 750 and the 500, are different from
15 engineering perspectives in that the filter
16 characteristic is different and the volume of
17 flow air pushed through them is also greatly
18 different.

19 BY MR. BANKSTON:

20 Q. Dr. David, can you pull out your
21 report for me and flip to page 20?

22 A. I'm there.

23 Q. Do you see at the top references to
24 some scientific work by Hall and by Zink?

25 A. Yes, I do.

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1 Y. DAVID

2 infection, and there's no correlation between
3 colorectal procedures and orthopedic surgical
4 procedure.

5 BY MR. BANKSTON:

6 Q. Okay. There was some testimony
7 today about the literature review conducted by
8 Dr. Wood and his associates. Do you know
9 which study I'm referring to there?

10 A. Yes.

11 Q. Okay. In that review, was there
12 information -- did it simply include studies
13 that were unfavorable to the Bair Hugger or
14 did it also include some studies that claimed
15 to be favorable to the Bair Hugger?

16 MS. EATON: Objection to the form.

17 A. As I sit here today, I don't
18 remember all the studies. There are probably
19 15. He looked at what's available in the
20 literature at the time he conducted his study,
21 but those are the -- representative of the
22 knowledge that was in the field at that time.

23 BY MR. BANKSTON:

24 Q. Okay. You're familiar -- we've
25 discussed much today -- there are multiple

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1 Y. DAVID

2 Q. Are you familiar with what these
3 studies are?

4 A. Yes.

5 Q. Okay. Can you briefly explain what
6 the context of these studies are?7 A. Yes. I read those articles. Hall
8 is talking about, I believe, eight volunteers
9 that were subjected to a culture count, and
10 Zink is talking about, I believe, 16 patients
11 that were in a completely different
12 environment than orthopedics procedure.13 Q. Dr. David, can you tell -- can you
14 tell the jury generally what your impression
15 of your task in this case was?16 A. Absolutely. And I actually put it
17 as the first paragraph in my report, that my
18 task was to review the hazards and risk
19 associated with the Bair Hugger 750 family and
20 to opine about if that would contribute to
21 unreasonable dangerous biomedical engineering
22 device that increase the probability of
23 infection in orthopedics procedure or not.24 Q. Okay. Can you tell me a little
25 bit -- no, let me take that back. In coming

1 Y. DAVID
 2 to an opinion about the -- whether a device
 3 more likely than not does or does not pose a
 4 patient risk, can you briefly summarize to the
 5 jury what you believe qualifies you to render
 6 those kind of opinions?

7 A. That would be an easy task,
 8 Counsel. That's something that I have been
 9 doing for over 30 years, especially at the
 10 Texas Medical Center where I worked 25 years.
 11 I was director -- I was the chairman of
 12 medical technology evaluation committee with
 13 the specific task of reviewing new technology
 14 and make recommendation to the hospitals
 15 should they acquire and invest in that
 16 technology because it will have benefit of
 17 lower risk of existing device or increasing
 18 patient outcome because of positive feature
 19 that they represent.

20 My committee consists of many
 21 representative stakeholders; physicians,
 22 nurses, purchasers, administrators, safety
 23 officers, risk control and quality control
 24 professionals, and facilities engineering,
 25 biomedical engineering, and sterile processing

1 Y. DAVID
 2 supplies.

3 So the committee was representing
 4 so many expertise and I was in the position
 5 where I had to receive their input and derive
 6 recommendation to the hospital management if a
 7 device is beneficial with lower risk than what
 8 is being used today or until that product
 9 come.

10 So I believe that I have the
 11 qualification based on academic training and
 12 experience working with these stakeholders and
 13 with this group to specifically evaluate and
 14 assess risk-benefit ratios.

15 Q. Do you feel like you have enough
 16 materials to give yourself an informed and
 17 helpful opinion that you can communicate to
 18 the jury?

19 A. I do. And when I felt that I don't
 20 have enough material, I approached you,
 21 Counsel, and requested specific documents or
 22 information. So I'm comfortable that I
 23 received the material that I need to arrive at
 24 the opinions.

25 Q. And do you feel confident today

1 Y. DAVID
 2 that your opinions were delivered to a
 3 reasonable degree of engineering probability?

4 A. I do.

5 MR. BANKSTON: Okay. That's all I
 6 have. You can pass -- pass the witness.

7 FURTHER EXAMINATION
 8 BY MS. EATON:

9 Q. Okay. Let's -- I just have a
 10 couple of things but perhaps let's go off the
 11 record for one second so I can organize
 12 myself.

13 THE VIDEOGRAPHER: We are going off
 14 the record at 18:34.

15 (Recess, 6:34 p.m. to 6:38 p.m.)

16 THE VIDEOGRAPHER: We are back on
 17 the record at 18:38.

18 BY MS. EATON:

19 Q. Dr. David, did you consult with any
 20 medical expert in connection with your work in
 21 this case?

22 A. No, I did not.

23 Q. Have you spoken with anyone who you
 24 believe to be an expert witness for any party
 25 in this case?

1 Y. DAVID

2 A. No, I did not.

3 Q. Okay. In performing your work for
 4 the hospitals, did you rely on physicians and
 5 nurses to provide you with information about
 6 clinical risks and benefits?

7 A. On the clinical side, yes.

8 Q. Do you understand that it was your
 9 responsibility, in preparing your report, to
 10 express all of the opinions that you would
 11 intend to offer at trial?

12 A. I do.

13 Q. And did you also understand that it
 14 was your responsibility to provide the bases
 15 for those opinions?

16 A. Yes.

17 Q. Did you endeavor to do that?

18 A. Absolutely.

19 Q. Okay. Are the statements that are
 20 contained in your report accurate to the best
 21 of your knowledge?

22 A. They are.

23 Q. Okay. Is there any prohibition on
 24 your discussing published literature with the
 25 hospital, to your understanding?

<p>1 Y. DAVID</p> <p>2 A. I'm trying to understand your</p> <p>3 question. Prohibition on published</p> <p>4 hospital...</p> <p>5 Q. If you had an interpretation of</p> <p>6 published literature about a forced-air</p> <p>7 warming device or any other device, would you</p> <p>8 be free to talk to a hospital about that?</p> <p>9 A. During this litigation, I don't</p> <p>10 feel so.</p> <p>11 Q. You simply can't speak at all about</p> <p>12 patient warming devices, to your</p> <p>13 interpretation?</p> <p>14 MR. BANKSTON: Object to the form.</p> <p>15 A. As it relates to the condition of</p> <p>16 this litigation, yes, that's the way I feel.</p> <p>17 BY MS. EATON:</p> <p>18 Q. Okay. Did you review an ECRI</p> <p>19 evaluation of the potential risk of infection</p> <p>20 with Bair Hugger use?</p> <p>21 A. Yes.</p> <p>22 Q. Did you cite that in your report?</p> <p>23 A. Good question. I don't think so.</p> <p>24 Q. Do you believe you reviewed it</p> <p>25 before you wrote your report or after?</p>	<p>1 Y. DAVID</p> <p>2 A. After.</p> <p>3 Q. Okay. Do you believe you reviewed</p> <p>4 it -- can you tell me when you reviewed it?</p> <p>5 A. I became aware that they made a</p> <p>6 report and wanted to understand what they</p> <p>7 considered, so I would say probably in the</p> <p>8 last month or so.</p> <p>9 Q. Are there any other materials</p> <p>10 related to this case that you reviewed in the</p> <p>11 last month that we haven't discussed here</p> <p>12 today and have not been identified for me</p> <p>13 today?</p> <p>14 A. No.</p> <p>15 Q. Okay. Did you agree with the</p> <p>16 conclusion of ECRI?</p> <p>17 A. I believe they attempted to</p> <p>18 understand the condition. They're operating</p> <p>19 in a different environment than I am, and they</p> <p>20 concluded that what I believe is that</p> <p>21 additional studies are needed.</p> <p>22 Q. They concluded that there was not</p> <p>23 sufficient evidence to determine that there</p> <p>24 was an increased risk with the Bair Hugger</p> <p>25 device, right?</p>
<p>1 Page 312</p> <p>2 Y. DAVID</p> <p>3 MR. BANKSTON: Object to the form.</p> <p>4 A. The way I understand their document</p> <p>5 or what I read is that they have not find</p> <p>6 material to recommend the discontinued use of</p> <p>7 the Bair Hugger and that additional studies</p> <p>8 are required to better address that issue.</p> <p>9 BY MS. EATON:</p> <p>10 Q. Did you disagree with anything</p> <p>11 about the method they used to identify</p> <p>12 information they reviewed?</p> <p>13 A. No.</p> <p>14 Q. Did they use a more comprehensive</p> <p>15 method than you used to identify literature?</p> <p>16 A. Counsel, they are doing different</p> <p>17 things than I'm doing. I think that I</p> <p>18 mentioned that this is a different</p> <p>19 environment. They have a relationship with</p> <p>20 industry, with hospital as customers, and</p> <p>21 they're looking at an overall.</p> <p>22 I have specific charge to my work.</p> <p>23 I'm not studying the complete concept of what</p> <p>24 is patient warming is all about. I have</p> <p>25 specifically charge as mentioned in the</p> <p>opening of my report.</p>	<p>1 Page 313</p> <p>2 Y. DAVID</p> <p>3 Q. Are you familiar with the</p> <p>4 proceedings of the international consensus</p> <p>5 meeting on periprosthetic joint infection? Is</p> <p>6 this something you've ever reviewed?</p> <p>7 A. Can I look at it?</p> <p>8 Q. Sure. Well, I mean, it's not cited</p> <p>9 in your report, and I just wondered if this is</p> <p>10 something that you recognize.</p> <p>11 A. No.</p> <p>12 Q. Did you make any attempts to look</p> <p>13 for industry evaluations or medical</p> <p>14 evaluations of the risk-benefit balance of the</p> <p>15 Bair Hugger device by an association, for</p> <p>16 example, or an organization?</p> <p>17 A. I think in my search I looked for</p> <p>18 that, yes.</p> <p>19 Q. Do you have any idea why you</p> <p>20 wouldn't have found the ECRI compilation or</p> <p>21 the proceedings of the periprosthetic joint</p> <p>22 infection? Is there something about your</p> <p>23 search that wouldn't have resulted in that?</p> <p>24 A. I don't think that the way I see</p> <p>25 that title, joint infection, would be</p> <p>something that would fall into my search.</p>

1 Y. DAVID
 2 Q. Okay. Were you looking
 3 specifically for literature that related to
 4 the risk of joint infection following surgery?
 5 A. No, I did not.
 6 Q. Is it your testimony that
 7 orthopedic surgery carries a higher risk of
 8 infection than colorectal surgery?
 9 A. It is my opinion that they are
 10 completely different conditions and present
 11 different challenges and cannot be compared.
 12 Q. Do you know if the infection risk
 13 for orthopedic surgery is higher or lower than
 14 the infection risk for colorectal surgery?
 15 MR. BANKSTON: Objection, form.
 16 A. No, I don't have that knowledge.
 17 BY MS. EATON:
 18 Q. Do you have any knowledge about
 19 what the risk of infection is with any type of
 20 surgery?
 21 A. I believe that I read recent
 22 statistics about that. Where was it...
 23 general statistics I read have the
 24 hospital-acquired infection, HAI, statistics
 25 relating to surgery. I don't remember as I

1 Y. DAVID
 2 sit here today specific numbers or quantities.
 3 Q. Okay. Are you an expert in -- I'm
 4 sorry. Have you made any -- have you made any
 5 effort to study, in connection with your work
 6 for this case, what are the various risk
 7 factors that might impact infection risk in a
 8 patient during surgery?
 9 A. When I read the articles, it was
 10 obvious that the beginning of the literature
 11 talk about the specific basic of infection
 12 routes and the sources. So every time I was
 13 reading the articles, it addressed that very
 14 clearly.
 15 Q. In terms of all the things that
 16 might impact patient infection risk from a
 17 medical perspective, that's not something
 18 you're offering opinions about?
 19 A. I am not.
 20 Q. Have you seen a 500 series filter?
 21 A. I don't know what you mean by
 22 "seen." I saw a drawing and I saw pictures in
 23 brochures.
 24 Q. Okay. Do you recall what shape it
 25 is?

1 Y. DAVID
 2 A. It's different than the 750.
 3 Q. Does it differ in size also from
 4 the 750?
 5 A. It does.
 6 Q. Have you done any comparison
 7 yourself of the filters?
 8 A. There's no need for me to do it.
 9 Other expert did that.
 10 Q. Who are you referring to?
 11 A. The literature here in front of us
 12 has ample support material for that, so
 13 Hanfield is one, three -- letters, letters
 14 from defendant officers is another one that --
 15 Q. I'm asking about anything you did,
 16 other than review materials.
 17 MR. BANKSTON: Object to the form.
 18 BY MS. EATON:
 19 Q. Did you make a comparison of the
 20 two filters? Maybe --
 21 A. There is --
 22 Q. You only looked at a drawing of the
 23 500 series filter. Is that correct?
 24 A. Right.
 25 Q. Okay. Do you recall what shape it

1 Y. DAVID
 2 was?
 3 MR. BANKSTON: Object to the form.
 4 A. Yeah.
 5 BY MS. EATON:
 6 Q. What shape was it?
 7 A. Square.
 8 Q. Do you recall the -- I'm sorry,
 9 what? Do you recall the size of it?
 10 A. I didn't realize I'm in a memory
 11 test here. Shape, geometry, size, it's all in
 12 the material here. It's all described in
 13 detail. It is part of the binders that I
 14 have. If you want to take the time, I will go
 15 through the material and find it.
 16 Q. I'd rather ask you a question about
 17 your report. If you --
 18 MR. BANKSTON: Object to the
 19 preamble.
 20 BY MS. EATON:
 21 Q. Do you have any -- actually, what
 22 is the basis for your opinion that the Bair
 23 Hugger device is adulterated and misbranded?
 24 What specific features of it?
 25 A. Very simply, the company misled the

<p>1 Y. DAVID</p> <p>2 FDA by suggesting that they are a comparable</p> <p>3 product, that they changed characteristics of</p> <p>4 major components like the filter, did not</p> <p>5 communicate that, and yet marketed the device</p> <p>6 to consumer, confusing and misleading them.</p> <p>7 Q. Do you have any basis for an</p> <p>8 opinion about industry standard other than</p> <p>9 compliance with FDA regulation?</p> <p>10 A. In regard to what?</p> <p>11 Q. In regard to the opinions you've</p> <p>12 expressed in your report.</p> <p>13 MR. BANKSTON: I think we're done,</p> <p>14 Counsel.</p> <p>15 MS. EATON: Could we just have an</p> <p>16 answer to this question?</p> <p>17 MR. BANKSTON: Well, you're already</p> <p>18 past it but I was trying to give you</p> <p>19 some grace. But you started asking more</p> <p>20 questions after you've already passed</p> <p>21 the --</p> <p>22 MS. EATON: I don't believe I've</p> <p>23 asked any question after I was past</p> <p>24 anything.</p> <p>25 Could we have that question read</p>	<p>1 Y. DAVID</p> <p>2 back, please.</p> <p>3 MR. BANKSTON: Can we get the time</p> <p>4 first?</p> <p>5 THE REPORTER: It's 7:01:42-43 at</p> <p>6 this point.</p> <p>7 (The reporter read back the</p> <p>8 following portion of the preceding</p> <p>9 record.)</p> <p>10 "QUESTION: Do you have any basis</p> <p>11 for an opinion about industry standard</p> <p>12 other than compliance with FDA</p> <p>13 regulation?</p> <p>14 "ANSWER: In regard to what?</p> <p>15 "QUESTION: In regard to the</p> <p>16 opinions you've expressed in your</p> <p>17 report?"</p> <p>18 (End of readback.)</p> <p>19 A. I'll have to search that.</p> <p>20 MR. BANKSTON: All right. I've got</p> <p>21 a few more questions.</p> <p>22 FURTHER EXAMINATION</p> <p>23 BY MR. BANKSTON:</p> <p>24 Q. This -- do you mind if I see that?</p> <p>25 Do you remember being asked about this?</p>
<p>1 Y. DAVID</p> <p>2 A. Yes.</p> <p>3 Q. And counsel wouldn't give it to</p> <p>4 you?</p> <p>5 A. Correct.</p> <p>6 Q. Because she said it wasn't in your</p> <p>7 report?</p> <p>8 A. Right.</p> <p>9 MS. EATON: Object to the form. I</p> <p>10 didn't say I wouldn't give it to him. I</p> <p>11 asked him if he recognized it.</p> <p>12 MR. BANKSTON: And then you said</p> <p>13 he's not getting it because it's not in</p> <p>14 his report.</p> <p>15 MS. EATON: He said, no, he didn't</p> <p>16 recognize it.</p> <p>17 BY MR. BANKSTON:</p> <p>18 Q. Counsel -- Dr. David, do you</p> <p>19 remember counsel telling you this wasn't in</p> <p>20 your report?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Can you go to page 48 for</p> <p>23 me. Can you read the fourth entry from the</p> <p>24 bottom for me?</p> <p>25 A. "International consensus meeting on</p>	<p>1 Y. DAVID</p> <p>2 periprosthetic joint infection."</p> <p>3 Q. Okay. So that is something you</p> <p>4 reviewed in this case?</p> <p>5 MS. EATON: Objection to the form.</p> <p>6 A. If it's listed here as document,</p> <p>7 yes.</p> <p>8 BY MR. BANKSTON:</p> <p>9 Q. The depositions that you reviewed</p> <p>10 in this case, did they have exhibits to them?</p> <p>11 A. Yes.</p> <p>12 Q. Do you remember in any of the</p> <p>13 depositions in this case or in more than one</p> <p>14 or none of them, was ECRI ever discussed in</p> <p>15 those depositions?</p> <p>16 A. Yes.</p> <p>17 Q. Now, in your report, you did not</p> <p>18 specifically list each and every exhibit of</p> <p>19 every deposition I see. That's correct?</p> <p>20 A. Correct.</p> <p>21 MS. EATON: Object to the form.</p> <p>22 BY MR. BANKSTON:</p> <p>23 Q. Okay. When reading the depositions</p> <p>24 that had exhibits, those exhibits that are</p> <p>25 discussed in the deposition, those are parts</p>

1 Y. DAVID
 2 of the transcripts that you've read?
 3 MS. EATON: Object to the form.
 4 A. Absolutely.
 5 BY MR. BANKSTON:
 6 Q. The exhibits in the depositions
 7 that you reviewed, did you consider them
 8 important in coming to your opinions?
 9 MS. EATON: Object to the form.
 10 A. Yes.
 11 BY MR. BANKSTON:
 12 Q. The exhibits that are in the
 13 depositions, do you consider them as materials
 14 that you have reviewed in coming to your
 15 opinions in this case?
 16 A. Very much so, yes.
 17 MR. BANKSTON: Okay.
 18 MS. EATON: Object to the form.
 19 MR. BANKSTON: And we get to go
 20 home, Dr. David.
 21 MS. EATON: No, sir. I have a few
 22 follow-up questions because what I've
 23 been provided doesn't include any
 24 exhibits at all and so I definitely have
 25 some questions.

1 Y. DAVID
 2 here today do not include any exhibits
 3 at all, and I've received repeated
 4 assurances that I have --
 5 MR. BANKSTON: That's strange
 6 because my --
 7 MS. EATON: They don't -- they're
 8 not contained with the depositions and
 9 I've asked if I've received all the
 10 materials and I've been told repeatedly
 11 yes. So I'd just make a request that we
 12 have a search for any additional
 13 materials that may have been reviewed
 14 because it would appear that there are
 15 quite a few that may be missing.
 16 MR. BANKSTON: All right. If you
 17 really think that you are hair-splitting
 18 enough to say that a person who has read
 19 depositions did not also review the
 20 exhibits that were discussed in the text
 21 of the deposition, I think that's an
 22 asinine position. I think providing
 23 notice of what depositions were --
 24 MR. GOSS: Let's not get into any
 25 name-calling.

1 Y. DAVID
 2 MR. BANKSTON: You can go to the
 3 Court for those.
 4 MS. EATON: I have a few follow-up
 5 questions.
 6 MR. BANKSTON: No, you don't.
 7 We're going.
 8 MS. EATON: Well, I'm going to ask
 9 and you --
 10 MR. BANKSTON: I'm going to tell
 11 you what's going to happen. We're going
 12 to go because Dr. David needs to go and
 13 he has a prior engagement. If you feel
 14 like you need to reconvene the
 15 deposition, you can attempt to do that
 16 through whatever legal avenues you
 17 believe are appropriate. But I can tell
 18 you what's going to happen right now is
 19 at 7:00 p.m., when you began a
 20 deposition late and have taken a lot of
 21 time preparing in between stuff, we're
 22 going to go right now. So that's what's
 23 going to happen.
 24 MS. EATON: For the record, the
 25 documents that have been provided for me

1 Y. DAVID
 2 MR. BANKSTON: Well, it is and I
 3 keep getting this kind of thing, so I'm
 4 going to --
 5 MR. GOSS: Put it on the record.
 6 Your objection is noted. I think we
 7 know where we stand on this --
 8 MR. BANKSTON: That's right.
 9 MR. GOSS: -- hopefully the
 10 position that he has --
 11 MR. BANKSTON: Right. As though a
 12 counsel would not know to ask about
 13 things discussed in a deposition when
 14 the depositions are listed in the
 15 materials reviewed, and that's why we're
 16 heading out today.
 17 MS. EATON: Okay.
 18 THE VIDEOGRAPHER: Christin, is
 19 that it?
 20 MS. EATON: Yes.
 21 MR. BANKSTON: Thank you, lady and
 22 gentlemen. This concludes the
 23 deposition. We're going off the record
 24 at 18:55.
 25 (Time noted: 6:55 p.m.)

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1 C E R T I F I C A T E			1 ----- INDEX -----		
2 STATE OF TEXAS)			2 Page		
3 COUNTY OF HARRIS)			3 EXAMINATION OF YADIN DAVID, Ed.D., P.E.,		
4 I, SUSAN PERRY MILLER, CSR, CCR,			4 C.C.E.:		
5 RDR, CRR, CRC, Notary Public in and for the			5 BY MS. EATON..... 5		
6 State of Texas, do hereby certify:			6 BY MR. BANKSTON..... 292		
7 That YADIN DAVID, Ed.D., P.E.,			7 BY MS. EATON..... 308		
8 C.C.E., the witness whose deposition is			8 BY MR. BANKSTON..... 319		
9 hereinbefore set forth, was duly sworn by me			9		
10 and that such deposition is a true record of			10 REPORTER'S CERTIFICATE 326		
11 the testimony given by the witness;			11		
12 That pursuant to Rule 30 of the			12		
13 Federal Rules of Civil Procedure, signature of			13 PREVIOUSLY MARKED EXHIBITS Ref. Page		
14 the witness was not reserved by the witness or			14 Exhibit 47 Previously Marked 298		
15 other party before the conclusion of the			15 Exhibit 48 Previously Marked 301		
16 deposition;			16 [Also Marked as		
17 I further certify that I am not			17 Exhibit 12 in this		
18 related to any of the parties to this action			18 Deposition]		
19 by blood or marriage; and that I am in no way			19		
20 interested in the outcome of this matter.			20		
21 IN WITNESS WHEREOF, I have hereunto			21		
22 set my hand this 11th day of August, 2017.			22		
23			23		
24			24		
25 SUSAN PERRY MILLER, RDR, CRR, CRC			25		
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1 ----- EXHIBITS -----			1		
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3 Exhibit 1 Subpoena to Produce 7 23			3		
4 Documents,			4		
5 Information, or			5		
6 Objects, or to Permit			6		
7 Inspection of Premises			7		
8 in a Civil Action			8		
9 Exhibit 2 Plaintiffs' Experts' 33 5			9		
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2 DAVID, Ed.D., P.E., C.C.E.
3 Case Name: In Re: Bair Hugger Products
4 Liability Litigation
5 Dep. Date: August 1, 2017
6 Deponent: YADIN DAVID, Ed.D., P.E., C.C.E.
7 Pg. Ln. Now Reads Should Read Reason

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24 Signature of Deponent
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